DOCTOR OF CLINICAL PSYCHOLOGY (DCLINPSY)

Doctorate in Clinical Psychology : Main Research Portfolio

1) The evidence for hospital based psychological interventions in the emergency department: a systematic review; 2) Service improvement project of a pilot Tier 2 weight management course, Balance'; 3) What 'are' the 'cognitive C behavioural 'predictors 'of 'recovery 'and persistence'of'dizziness'following'assessment'at'an'NHS'vestibular'clinic?

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Chapter 1: Critical Review of the Literature

The evidence for hospital based psychological interventions in the emergency department: a systematic review

Registration

This systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 29th March 2018 (registration number CRD42018087860).

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Abstract

Objective: This systematic literature review surveyed the evidence for psychological interventions initiated in the emergency department (ED) and completed within the hospital setting. The review considered the types of clinical problems treated and aspects of the intervention including type, delivery personnel, duration, effectiveness and patient satisfaction. The impact on frequent attendance in the ED was also considered. **Method:** The review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 29th March 2018 (registration number CRD42018087860). A systematic search of three databases (APAPsychNet, Cochrane and PubMed) identified 1923 potential studies for inclusion, of which 43 proceeded to full review. Eighteen papers met the full inclusion criteria and twenty-four relevant papers were discussed for completeness. **Results**: Studies covered six clinical presentations: trauma/ PTSD-prevention, panic/non-cardiac chest-pain; health anxiety, health behaviour change and 'medically unexplained' symptoms. Results suggested that it is feasible to offer psychological interventions in the ED and there is evidence of effectiveness, reducing frequent attendance and increasing patient satisfaction – even when interventions are ineffective. **Conclusions**: There is evidence for the feasibility of initiating effective psychological interventions within the ED across a range of clinical presentations. Available studies are of mixed quality and further high quality research is needed to determine what is effective and feasible in the ED.

Key words: Emergency department; accident & emergency; psychological therapies; systematic review.

Background

In England in 2016, there were 23.57 million attendances in emergency departments (ED), 65% of which were visits to major ED centres. Between 2004/05 and 2014/15 attendance at major ED centres rose by 10%. The highest growth in attendances has been seen in walk in/minor injury units (known as Type 3 centres) compared to major ED (Type 1) or specialist facilities (Type 2). People aged >80 are most likely to attend the ED and research shows that the ED presentations of older adults are characteristically different, with problems being more urgent, being medical rather accident-related, and requiring a longer period in the ED (Salvi et al., 2007). Of working age adults, those aged 20-24 have the highest attendance. On average, one-fifth of ED attenders are ≥65 and one-quarter are aged ≤19 (House of

Commons briefing paper, 2018). The context of ED clinical service delivery is one where waiting times are of significant political, public and regulatory interest (The King's Fund, 2017) and ED waiting times in England have increased substantially for example in 2017 16.5% of attendees spent more than than 4 hours in the ED compared with 5.6% in 2012 (House of Commons briefing paper, 2018). Demand has increased and one factor thought to be important is that system fragmentation and inconsistent local provision leads patients to access the ED rather than community services (NHS England, 2013) indicating the importance of health service system design and the need for innovation.

Contributing to this picture are patients who regularly access the ED known as frequent attenders (FA), a group which includes those with chronic health conditions, mental health problems and substance misuse problems and those with complex social needs. The Royal College of Emergency Medicine (RCEM) has issued best practice guidance on supporting FA in the ED, including care plans, case management, multi-disciplinary working, involving primary care and providing psychological therapies (RCEM, 2017). Care plans are an individual patient record of health and care, which can reduce costs by preventing unnecessary investigations (RCEM, 2017). Case management refers to involving the wider system to support FA with issues beyond health such as housing and social care (RCEM, 2017). Multi-disciplinary case conferences to share information and plans are also recommended, along with increasing involvement of primary care practitioners to prevent repeated attendance. Guiding FA with 'medically unexplained'/persistent physical symptoms towards evidence-based psychological therapies is recommended best practice (RCEM, 2017). However there is insufficient evidence to conclude whether these practices are effective for reducing frequent attendance (RCEM, 2017).

Another sub-set of patients whose needs might be better served in non-ED settings, are those who interpret their symptoms as requiring urgent medical attention when in fact they are symptoms of anxiety (Daniels & Sheils, 2017). Due to the physiological presentation of anxiety, it is not uncommon for patients to misinterpret physical symptoms as signs of serious illness. Patients experiencing heart palpitations may catastrophically misinterpret these symptoms as a sign of an imminent threat such as a heart attack (Clark, 1988). Physical symptoms or bodily sensations may be interpreted as evidence of a non-imminent health threat which which requires medical investigation, known as illness anxiety (Daniels & Sheils,

2017).

The cost implications of these presentations has been explored in a retrospective cohort study looking at undiagnosed panic disorder in the ED (Coley, Saul, & Seybert, 2009). The results showed that patients with NCCP and who had most likely been experiencing panic (n=155) had not actually been screened or treated for panic, and 28% of these patients returned to the ED in the following year. These patients accounted for a significant amount of hospital resource usage. The efficacy of psychological interventions for such presentations is established, further demonstrating the importance of recognising and treating problems with underlying psychological causes. For example, CBT is effective for health anxiety in medical conditions (Tyrer, Tyrer, & Lovett, 2011), non-cardiac chest pain (NCCP) (Jonsbu, Dammen, Morken, Moum, & Martinsen, 2011) and panic disorder (PD) (Kenardy et al., 2003).

There are patients whose needs are not met in the ED either because their problem does not require urgent medical care or because it is a non-medical problem such as someone with complex social and mental health difficulties. Others may benefit from interventions which are not always available in the ED, for example, CBT for medically unexplained symptoms (King's Fund, 2017). This unmet need can lead to re-presentation which has cost implications. It is also important to note that 50% of ED attenders in the UK leave either without medical intervention, or with advice and guidance only (King's Fund, 2017). There is evidence to suggest that psychological intervention can be beneficial for patients in each of these groups, yet such treatments are not often available within the ED or the hospital setting.

The role of psychology in urgent care

Evidence from systematic reviews shows that ED attendance can be an opportunity to offer psychological intervention, for example, to encourage health behaviour change in alcohol misuse (D'Onofrio & Degutis, 2002; Nilsen et al., 2008; Taggart, Ranney, Howland, & Mello, 2013) and smoking cessation (Pelletier, Strout, & Baumann, 2014). Effective ED-based interventions include screening and brief motivational interviewing for alcohol use (D'Onofrio & Degutis, 2002) and self-help, motivational-interviewing, counselling and nicotine replacement therapy for smoking cessation (Pelletier et al., 2014). The smoking cessation interventions were associated with higher smoking cessation rates than those reported in national

survey data however results could not be compared due to the lack of standardised controls (Pelletier et al., 2014). The MI for alcohol usage review only included four studies but all suggested feasibility and showed effectiveness for decreasing alcohol consumption and other negative consequences of alcohol use (D'Onofrio & Degutis, 2002).

The results of a review of non-pharmacological pain interventions delivered in the ED showed a diverse range of interventions, including active management advice, acupuncture, deep breathing and music therapy (Sakamoto, Ward, Vissoci, & Eucker, 2018). The review indicates that the ED is a suitable place for delivering non-medical interventions. Twenty-three out of 56 studies reported reduced pain following intervention, 24 showed no difference and 9 studies had no controls. The meta-analysis showed that the non-pharmacological interventions were more effective than the control (standard mean difference 0.46 (95% CI -0.65 to -0.27)) (Sakamoto et al., 2018). However, a limitation is that the review includes a heterogeneous group of small studies which were susceptible to bias.

Clinical psychologists work in a range of physical health services including oncology, stroke, endocrinology, renal medicine, obesity, neurology and gynaecology (BPS, 2008) with service settings including both inpatient, outpatient and emergency departments. As an indication, a survey (N=89) of UK clinical health psychologists working in physical health settings (BPS, 2015) found that 23.5% (n=20) of psychologists worked in trauma/intensive care settings. Although the inclusion of intensive care in these figures extends beyond the scope of the ED, it indicates that clinical psychologists are present in emergency settings. In response to a lack of psychological provision within the ED the Improving Access to Psychological Therapies service (IAPT) was integrated with an ED in 2011 in South Australia, in a service called IAPT@Flinders which offers CBT to ED patients (Bastiampillai et al., 2014) a service which helps ED practitioners to close the gap in psychological provision. Outcome data is yet to be published on the efficacy of this service, but the initial qualitative report describing the service set-up provides evidence of feasibility and states that over a 20-month period the service received 658 referrals and 434 of these patients received treatment (Bastiampillai et al., 2014).

In addition to psychology services, psychiatric liaison teams (PLT) operate within hospital settings and the ED. PLTs support patients with a range of difficulties including mental health, drug-alcohol problems, and medically unexplained

symptoms (Joint Commissioning Panel for Mental Health, 2012). Service commissioners state that the PLT should include a clinical psychologist and brief psychological interventions should be offered to patients (Joint Commissioning Panel for Mental Health, 2012). However, psychologists are not always part of PLTs (Aitken, 2007) and evidence-based psychological treatments are not always available.

An emergency psychological response team called *SAMUR-Protección Civil* operates in Madrid where psychologists work alongside emergency practitioners including paramedics (Bell, 2010) with the psychologists' duties including psychological interventions and staff training (Bell, 2010). Quantitative outcome data is yet to be published however between 2004 and 2008 the service attended more than 4500 incidents and staff report suggests that the service is welcomed by both patients and emergency practitioners (Bell, 2010). A qualitative summary of interventions following international human-made and natural disasters reported the use of psychosocial interventions (Reifels et al., 2013) where low intensity responses included psychological first aid, social support and psychoeducation, and high intensity responses included long-term psychotherapy and psychiatric medication. Although overall effectiveness data was not provided, the report recommended that mental health professionals are part of a disaster response but noted that further research is required to determine intervention efficacy (Reifels et al., 2013).

Aims of this review

Given that there is an unmet psychological need within the ED, that psychological interventions are effective for presentations seen in the ED, and that psychological interventions are delivered in emergency and disaster settings, this review aimed to survey the evidence for psychological interventions initiated in the ED, to identify gaps and promising findings and to discuss the implication for clinicians and service development. The scope included interventions started in the ED and completed within the hospital setting in order that the results could include longer-term psychological interventions if relevant.

The review asked: what is the evidence-base for psychological interventions initiated in the ED and completed within the hospital setting? More specifically:

1. Which clinical presentations are treated?

2. Where in the hospital are these interventions delivered?
3. Who delivers these interventions?
4. What is the duration of these interventions?
5. Which types of interventions are offered and how effective are they?
6. What is the impact on frequent ED attendance?
7. How acceptable and satisfactory are these interventions to patients?
8. What are the implications for clinical practice and service development?

These review questions were informed by previous systematic reviews of psychological interventions (Pelletier et al., 2014; Smith, Sonego, Ketcheson, & Larson, 2014).

Method

This systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 29th March 2018 (registration number CRD42018087860).

Search strategy

A review protocol was developed and a database search was conducted by the lead author on 15th March 2018, using three electronic databases: Cochrane, PubMed and APAPsycNet. There were no restrictions on date, language or publication status. The following query was used in all three databases: *"emergency department"* OR *"emergency room"* OR *"accident and emergency"* OR *"accident & emergency"* OR *"A&E"* OR *"emergency medicine"* OR *"emergency/urgency"* OR *"urgency/emergency"* AND *"cognitive therapy"* OR *"behavior therapy"* OR *"behaviour therapy"* OR *"behavioral therapy"* OR *"behavioural therapy"* OR *"psychotherapy"* OR *"psychodynamic therapy"* OR *"clinical psychology"* OR *"cognitive behavioral therapy"* OR *"cognitive behavioural therapy"* OR *"behavioral medicine"* OR *"behavioural medicine"* OR *"psychological intervention"* OR *"psycho education"* OR *"problem solving therapy"* OR *"problem solving skills"* OR *"self help".*

Eligibility criteria

All study designs were eligible for inclusion. Included studies were in English but there were no date restrictions. Studies needed to include a quantitative outcome measure (unspecified) and qualitative studies, reviews and book chapters were excluded. Participants were defined as being aged 18-65 and there were no gender exclusions. All clinical presentations were included except for alcohol and substance misuse, deliberate self-harm, para-suicide and psychiatric presentations. If participants had a co-morbid physical and mental health problem (e.g. chest pain and depression) this was included, but studies were excluded if the primary reason for presentation was not a physical health problem (e.g. psychiatric crisis). Studies needed to include a psychological intervention (which was defined broadly and inclusively) and interventions were delivered directly by the hospital practitioner or patient (e.g. self-help) but without the need for a third party (e.g. carers/family members). Mixed interventions were included if there was a psychological component (e.g. medication plus psychological therapy was included, medication alone was not). All delivery modes and methods were included e.g. individual, group, face-to-face, telephone. Patients were identified within the ED and interventions were completed within the hospital setting (or at home if self-help) but without the need for the practitioner to leave the hospital.

Selection process

Database results were extracted into EndNote and then to Covidence and duplicates were removed at each stage. The lead author screened all abstracts and twenty percent of the abstracts (n=289, sample selected by random number generation) were reviewed by a final year trainee Clinical Psychologist (SL). There were four disagreements between the authors (Cohen's k: 0.74, indicating substantial agreement) and all were resolved following a discussion about the inclusion/exclusion criteria. The lead author then reviewed all abstracts against inclusion / exclusion criteria resulting in 43 studies. Forty-three papers then went forward for a full text review, where the full content was reviewed to determine whether the paper met inclusion/exclusion criteria, resulting in twenty-four studies. Two additional papers were identified by hand search but these did not meet criteria.

In terms of quality assurance of the selection process, 20% of the full papers (n=8, sample selected by random number generation) were reviewed by the same second researcher (SL). There was one disagreement between the raters (Cohen's

k: 0.75, indicating substantial agreement) which was resolved following a discussion about the inclusion/exclusion criteria.

Contact with authors

During the full text review and data extraction stages, eight authors were contacted for clarification, e.g. to clarify where the intervention was carried out, participant age or another clarification. Six authors replied and the information was used to inform the selection process or the analysis. For the two studies where responses were not received (relating to sample age), an inclusion/exclusion decision was made and this is discussed more fully in the results and limitations sections.

On completion of the search, corresponding authors of the included papers were contacted to identify any unpublished papers. Twenty authors were contacted and after three weeks the responses were as follows: uncontactable (n=5); no response (n=8); responded but not suggesting additional papers (n=2); responded providing additional references or suggestions for authors to contact (n=5). The new references were reviewed but did not meet inclusion criteria.

Data extraction process

The lead author independently extracted the data into three evidence tables. Data items included: study characteristics (author and year, country, title, design, sample size, sample age, sample gender, outcome measures); intervention detail (intervention format, intervention content, theoretical underpinning, recruitment setting, delivery setting, delivery personnel) and study outcomes (results, follow-up, impact on frequent attendance if stated, conclusion). Quantitative analysis was not completed due to the heterogeneity of studies but study outcomes are reported in the evidence tables and discussion (Appendix B).

Analysis plan

A narrative synthesis was planned. Study details were extracted in line with review aims and tabulated into three groups according to clinical presentation. A meta-analysis was also planned but this was not conducted due to the heterogeneity of the results.

Risk of bias

The lead author independently conducted a risk of bias assessment using the Cochrane risk of bias tool (Higgins & Green, 2011) which is a tool designed to assess the risk of bias in randomised controlled trials. Each paper was assessed as 'high', 'low' or 'unclear', on five domains: selection, performance, attrition, reporting and other biases. A second researcher (SL) independently conducted a risk of bias on 20% of the included papers. This assessment was not used as an inclusion screening tool but was used to gather information pertaining to quality and risk of bias.

Results

Search results and inclusion in study

The search results are shown at Figure 1. After duplicates were removed, 1923 records (titles and abstracts) were screened. These records were reviewed in Covidence and records were included if they appeared to meet the inclusion criteria. At this stage, 1880 records were excluded, 43 full texts were taken forward for full text review and 18 studies were eligible for inclusion. However, 6 studies which had been excluded on age criteria at full text review were also included for discussion, totaling 24 included studies. This decision is explained below.

Exclusion due to age. The planned age inclusion/exclusion criteria was that studies would be included if the age inclusion criteria matched the review's criteria (18-65) or if the age range of the sample was stated within the paper and this fitted with the review's criteria.

Five studies did not meet the age inclusion/exclusion criteria but were discussed for completeness: one study had a lower age inclusion of <18 years (Zatzick et al., 2015), and four studies stated that the the upper age inclusion or the sample age was >65 years (Esler, 2001; Marchand et al., 2012; Turpin, Downs, & Mason, 2005; and Tyrer. et al., 2011). The decision to include these studies for completeness aimed to reduce bias, because the review included studies where the sample age range or upper age inclusion criteria was not stated - which could potentially mean including participants aged over 65. Over-inclusion (where age was unclear) rather than under-inclusion was thought to be important as this was the first review of its kind - but this is acknowledged as a limitation. Sample age information is noted in the summary tables for reference.

Related and overlapping studies. In the trauma-group of studies, the PTSD prevention study by Des Groseilliers, Marchand, Cordova, Ruzek, and Brunet (2013) is a follow-up study of Brunet, Des Groseilliers, Cordova, and Ruzek (2013).

Also in the trauma group, one study was excluded at data extraction stage (Price, Kearns, Houry, & Rothbaum, 2014) as it was secondary analysis of an included study (Rothbaum et al., 2012).

In the NCCP / panic group, a group of five related studies were found. These studies had samples aged over 65 but were included for discussion as described above. Two studies appeared to use partially overlapping samples (Lessard et al., 2011; Pelland et al., 2011) and follow-up study of these papers was found (Marchand et al., 2012). Two studies were excluded as they used secondary analyses of the follow-up study (Marchand et al., 2012) and the study foci were less relevant: sleep quality (Belleville et al., 2015) and cost-effectiveness (Poirier-Bisson et al., 2013).

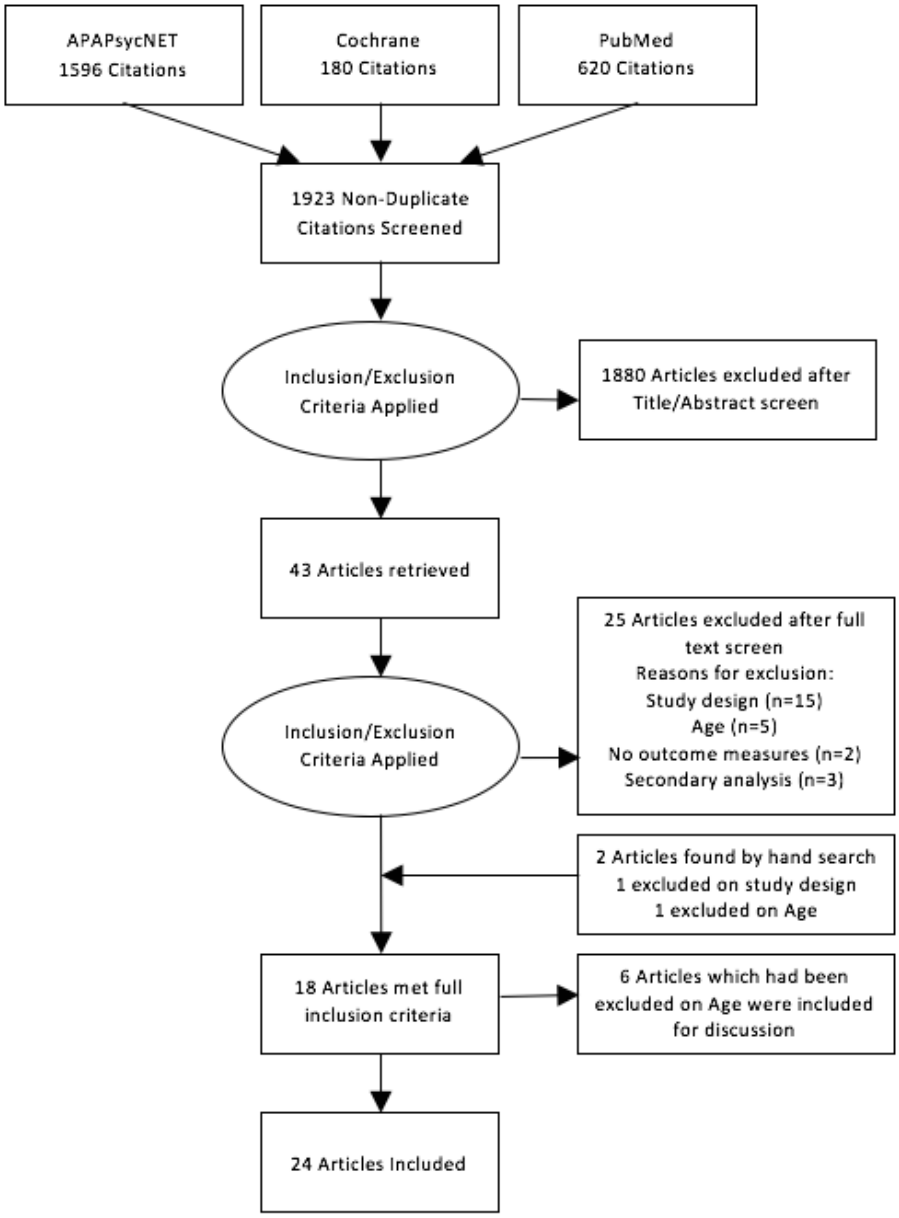

Figure 1. Systematic search results

Quality assessment

The results of the risk of bias analysis is presented in Table 1 (two follow-up studies were excluded). Eight out of 22 studies had a high risk of bias for selection bias including both sequence generation (allocation to interventions) and allocation concealment and for 2/22 these were unclear. All studies had a high risk of bias for blinding as blinding is not possible in psychological studies. Twelve out of 22 had a high risk of bias for blinding of outcome assessors and for 6/22 this was unclear. Nine out of 22 studies were deemed to have a high risk of bias for handling

incomplete data and for 8/22 studies this was unclear. Selective outcome reporting could not be accurately assessed as study protocols were not obtained. Other biases including sampling bias were found in 15/22 studies.

Table 1.

Risk of bias assessment

ID	Author & Year	Sequence Generati	Allocation concealment	Blinding of participan	Blinding of outcome	Incomplete outcome data	Selective outcome reporting	Other bias
1	Bugg (2009)	Low	Low	High	Unclear	High	Unclear	High
2	Brunet 2013)	Low	Low	High	Unclear	High	Unclear	Low
4	Iyadurai (2018)	Low	Low	High	Unclear	Low	Unclear	Low
5	Scholes (2007)	Low	Low	High	High	High	Unclear	Low
6	Turpin (2005)	Low	Low	High	High	High	Unclear	High
7	Wu (2014)	Low	Low	High	High	High	Unclear	Low
8	Rothbaum (2012)	Low	Low	High	High	High	Unclear	Low
9	Rothbaum (2008)	High	High	High	High	High	Unclear	High
10	Post (2017)	Unclear	Unclear	High	High	Low	Unclear	High
11	Zatzick (2015)	Low	Low	High	Low	Low	Unclear	High
12	van Beek (2013)	Low	Low	High	Low	High	Unclear	High
13	Dyckman (1999)	High	High	High	High	Unclear	Unclear	High
14	Nuthall (2007)	High	High	High	High	Unclear	Unclear	Low
15	Swinson (1992)	Unclear	Unclear	High	Unclear	Unclear	Unclear	Low
16	Hegel (1989)	High	High	High	High	Unclear	Unclear	High
17	Esler (2001)	Low	Low	High	Unclear	Unclear	Unclear	High
18	Tyrer (2017)	Low	Low	High	Low	Low	Unclear	High
19	Lessard (2012)	High	High	High	Unclear	Low	Unclear	High
20	Pelland (2011)	High	High	High	High	High	Unclear	High
22	Katz (2017)	Low	Low	High	Unclear	Unclear	Unclear	High
23	Abbass (2009)	High	High	High	High	Unclear	Unclear	High
24	Daniels & Sheils (2017)	High	High	High	High	Unclear	Unclear	High

Participants characteristics

The sample size in included studies was 2403. Sample size ranged from 1 to 411 participants, with a mean sample size of 100.1 (SD 107.7) (Table 2). All studies reported sample gender and age and details are provided in Appendix B.

Table 2

Number of participants per group of studies

Group of studies	Total no. in psychological intervention group(s)	Total no. in control or comparison groups	Total no.
Trauma/PTSD prevention (11 studies)	605 (*M* 55.0, SD 44.6)	710 (*M 64.5*, SD 68.3) (1 study did not have a control or comparison)	1379 (*M* 125.3, SD 124.0)
Panic/NCCP (10 studies)	331 (*M* 33.1. SD 17.82)	229 (*M 22.9*, SD 15.38) (1 study did not have a control or comparison)	833 (*M* 83.3, SD 257.89)
Other (3 studies)	191 (*M* 63.7, SD 70.5)	0 (3 studies did not have a control or comparison)	191
TOTAL	1127 (*M* 47.0, SD 39.6)	939 (*M* 39.12, SD 52.4)	2403 (*M* 100.1, SD 107.7)

Study characteristics

The studies were grouped into three according to clinical presentation (numbers of studies): trauma/PTSD-prevention (n=11); panic and NCCP (n=10), and other (n=3) including 'medically unexplained' symptoms; health anxiety in the context of a physical health problem and health behaviour change in a cardiac setting. The studies originated from five countries: USA (n=8), UK (n=7), Canada

(n=5), China (n=1) and The Netherlands (n=1). In terms of study designs, there were: RCTs (n=10), clinical non-RCT studies (n=9), case studies (n=3); follow-up studies (n=2). Table 3 provides an overview of included studies and further details are provided in Appendix B.

Table 3

Summary of studies

Study ID	Author & Year	Intervention type	Study Design	Sample	Key measures	Intervention	Delivery setting	Delivery personnel	Results	Frequent attendance impact
Clinical Presentation: Trauma/PTSD Prevention										
1	Bugg (2007) UK	Self-help following trauma	RCT	148 participants Two groups: Writing group (n=72) Information group (n=76)	Post-traumatic Diagnostic Scale (PDS) Hospital Anxiety and Depression Scale (HADS)	Writing intervention group : 1 x 1 hour appointment to receive instructions for writing and completed a 20-min writing exercise followed by the post-writing questionnaire. Participants then completed two further writing sessions at home on consecutive days.	At home (self-help)	Trainee Clinical Psychologist	Results were non-statistically significant	N/A
2	Brunet, A. et al. (2013). Canada	CBT following trauma	RCT	83 participants Two groups: Intervention group (n=44) Control group (n=39)	Impact of Event Scale-Revised (IES-R)	Two-session manualised intervention. Duration: 90 min & 75 min. Control: no intervention, questionnaires only.	Hospital	Social worker or nurse	Controlling the improvement in controls lead to an effect size of d = 0.39 in the intervention.	N/A
3	Des Groseilliers et al. (2013) Canada (NB This is follow-up of Brunet et al. 2013)	CBT following trauma (follow-up)	Follow-up study	46 participants (70% of original study). Two groups: Intervention group (n=26), Repeated assessmen control group (n=20)	Impact of Event Scale-Revised (IES-R)	Participants completed a 2-hour audiotaped clinical interview at the psychiatric hospital or at thei patient's home. Participants also filled out several self-report questionnaires in French or in English.	N/A follow up	Research assistant	Decreased in self-reported PTSD symptoms (IES-R) in the treated group at 2-year follow-up when compared with the control group (p0.008).	N/A
4	Iyadurai, L.. et al. (2018) UK	Computer game PTSD-prevention intervention following trauma	RCT	71 participants Two groups: intervention group (n=37) and control group (n=34)	Total no. of intrusive memories self-report Impact of Event Scale-Revised (IES-R); Post-traumatic Diagnostic Scale (PDS) Hospital Anxiety and Depression Scale (HADS)	Intervention: a reminder cue for the traumatic event followed by playing Tetris. Duration: Tetris game play time for at least one uninterrupted period of minimum of 10 min and for ~ 20 min in total. Control: Participants filled a pen & paper log of activity they had engaged in withn the ED of similar duration to intervention condition.	ED	Clinical Psychologist	Fewer intrusive memories were recorded by intervention participants 1-week post accident when compared to controls (p=0.005, d=0.67). 1-week follow-up showed that intervention participants had lower distress caused by intrusions in comparison to controls (d=0.54). Small to negligible effect sizes were found for all other measures at follow-up.	N/A
5	Scholes et al.(2007) UK	Self-help following trauma	RCT	411 participants Three groups: High risk intervention HI (n=116) High risk control - HC (n=111) Low risk control - LC (n=120).	Post-traumatic Diagnostic Scale (PDS) Hospital Anxiety and Depression Scale (HADS)	Two groups: high-risk intervention (HI) and high-risk control (HC). Non-eligible patients were allocated to a low-risk control group (LC). Participants sent questionnaires within 1 month of their accident. The HI group were also sent the self-help booklet and instructed to complete the questionnaires before reading the booklet.	At home (self-help)	Trainee Clinical Psychologist	Decrease in PTSD, anxiety and depression (p <0.001) across time. No group differences in these or quality of life measures.	N/A
6	Turpin et. al. (2005) UK	Self-help following trauma	RCT	291 participants Two groups: intervention (n=146) control (n=145)	Post-traumatic Diagnostic Scale (PDS) Hospital Anxiety and Depression Scale (HADS)	Intervention group sent a self-help booklet. Control group sent a letter without the patient information. Control participants offered a copy of the self-help booklet at the end of the study.	At home (self-help)	Trainee Clinical Psychologist	Decrease in PTSD anxiety and depression (p<0.05) over time. No group differences in PTSD or anxiety. Control group was less depressed (p<0.05) at follow-up. Reduction in PTSD caseness in controls (50%) compared with the intervention (20%), close to significance (p<0.06).	N/A
7	Wu, K. (2014) China	CBT following trauma	RCT	60 participants Two groups: B-CBT group (n=29) Self-help group (n=31)	Impact of Event Scale-Revised (IES-R) Hospital Anxiety and Depression Scale (HADS)	B-CBT 4 x 1.5 hour weekly session. Manualised therapy.	Clinical psychology outpatient department	Clinical Psychologist	B-CBT group: greater reductions in anxiety at 3-month and 6-month follow-up. Also, reduced depression at 6-month follow-up. Higher pretreatment anxiety and depression predicted negative outcome at 6-month follow-up in self-help group. No differential effect on PTSD symptoms (IES-R).	N/A

Study ID	Author & Year	Intervention type	Study Design	Sample	Key measures	Intervention	Delivery setting	Delivery personnel	Results	Frequent attendance impact
8	Rothbaum et al. (2012) USA	Exposure therapy following trauma	Randomised pilot study	137 participants Two groups: Intervention group (n=69) Assessment only group (n=68)	PTSD Symptom Scale-Interview Version (PSS-I) Beck Depression Inventory(BDI) Posttraumatic Stress Diagnostic Scale(PDS)	Initial assessment then random assignment to either intervention or assessment-only groups. Intervention provided immediately. Patients received 3 x 1 hour sessions of a modified PE intervention, distributed 1 week apart. Intervention included homework assignments.	ED	Trained therapists	Significantly lower PTSD symptoms in the intervention group at 4 weeks postinjury (p .01) . Improvements also seen at further follow-up: 12 weeks postinjury (p .05). Significantly lower depression seen at week 4 compared to the assessment group (p .05). The intervention was the most effective in PTSD reduction in rape victims at week 4 (p .004) and week 12 (p.05).	N/A
9	Rothbaum et al. (2008) USA	Exposure therapy following trauma	Non randomised pilot study	10 participants Two groups: Intervention group (n=5) Assessment only group (n=5)	PTSD Symptom Scale-I (PSS) PTSD Diagnostic Scale (PDS) Beck Depression Inventory (BDI) State-Trait Anxiety Inventory (STAI) Clinical Global Improvement Scale (CGI)	Intervention: 1-session abbreviated imaginal exposure intervention (duration not stated).	ED	Research clinicians (supported by ED staff)	Trend towards decreased depression (BDI) in the intervention group (pre-to-post treatment) and in addition, a decrease in clinician-rated symptom severity was found at at 1-week follow-up. Trend towards increased depression in the assessment group, plus non-significant increase in anxiety from pre- to post assessment.	N/A
10	Post, Loren M. et al. (2017) USA	Exposure therapy following trauma	Case study	1 participant	Psychological: PTSD Symptom Scale (PSS) Beck Depression Inventory (BDI) Psychobiological: Skin conductance (SC) fMRI - go/no-go task to assess behavioural inhiibition Fear Potentiated Startle (FPS) paradigm to assess startle response	1 x 1 hour exposure session plus homework task	ED	Therapist	Post intervention, participant did not display symptom worsening or develop PTSD even though risk factors had been apparent.	N/A
11	Zatzick (2015) USA	Technology enhanced care following trauma	RCT	121 participants Two groups: Intervention group (n=60) Usual care group (n=61)	Post-traumatic disorder checklist (PCL-C) Patient Health Questionnaire-9 Depression (PHQ-9)	Duration: Ongoing care over 6 months, IT element had a median duration of 2.25 hours per patient. Intervention participants given a laptop and guidance on web and smartphone applications. Care manager collaboratively developed a treatment plan with patient. Patients stepped up as clinically indicated. A computerised clinical decision support tool was also used. Usual care group: Usual care (routine outpatient surgical, primary care, and ED visits, and mental health services) + given a study laptop)	Medical Centre Level I trauma centre inpatient surgical ward or ED	Doctoral-level care management and behavioral therapists & medical pharmacotherapists	Modest but non-significant symptom reductions (p = .055) in intervention group. Significant result on covariate adjusted regression (p = .049). PTSD intervention effect was greatest at the 3-month (d = 0.35, p = .044) and 6-month (d = 0.38, p = .044) time points.	N/A
Clinical Presentation: Panic and/or Non-cardiac chest pain										
12	van Beek et al, (2013) The Netherlands	CBT for depression and panic disorder in chest pain	RCT	113 participants Two groups: Intervention CBT group (n=60) Treatment as usual group (n=53)	Assessor-rated clinical global impression severity scale (CGI-severity) Hamilton depression rating scale (HDRS) Hospital anxiety and depression scale (HADS); (HADS-A) and depression (HADS-D) State-trait anxiety inventory (STAI) Fear questionnaire (FQ)	6 x 45 minute sessions of CBT guided by a manual	Outpatient setting	Clinical Psychologists	CBT was superior after 24 weeks in reducing disease severity (p<.001) when compared to TAU. Positive effects also seen on: TAU on HAM-D (p<0.001),HADS-A (p< .001) and STAI-T (p<0.001). No significant differences on the HADS-D, STAI-T, and FQ.	N/A
13	Dyckman et. al (1999) USA	Psychological intervention for Panic	Quasi-experimental study	354 participants. Three groups: Intervention brochure group (n=53) Intervention contact group (n=32) Control group (n=269)	ED & hospital usage data	Groups received usual care plus: Brochure group - received a brochure & psychiatric referral. Contact group - received brochure, psychiatric referral and immediate consultation from psychistry department personnel about panic (1 x 20-30mins session)	ED	ED personnel or trained educator from psychiatric department	Statistically significant decrease in ED usage in contact group (p =0.0017) in comparison to the brochure condition, but not with the control (p=0.0672). Increase in ED use among patients given brochure only.	Rreduced ED attendance in contact group. All groups increased attendance in other departments.
14	Nuthall (2007) UK	CBT to prevent panic disorder	Quasi-experimental study	27 participants Two groups: Intervention group: (n=12) Control group (n=9)	Panic Disorder Severity Scale - Self-Report (PDSS-SR)	1 x 45 minute session	ED	Cognitive behavioural therapist	PDSS-SR scores showed no significant differences between intervention (p=.208) and control (p=.427) at 3-month follow-up. However, when additional CBT was provided, panic symptoms reduced.	N/A

Study ID	Author & Year	Intervention type	Study Design	Sample	Key measures	Intervention	Delivery setting	Delivery personnel	Results	Frequent attendance impact
15	Swinson (1992) Canada	Exposure treatment for panic	Quasi-experimental study	33 participants Two groups: Exposure instruction group (n=17) Reassurance group (n=16)	Fear Questionnaire (FQ) agrophobia subscale Mobility Inventory (MI) Beck Depression Inventory (BDI) No.of panic attacks (self-assessment)	1 x 60 minute session of reassurance or reassurance + exposure instruction	ED	Research project Psychiatrist	Intervention exposure group improved on measures of depression (p<0.002), avoidance (p<0.003) and panic frequency (p,0.03) over 6-months. Group receiving Reassurance only did not improve and reported worse agoraphobic avoidance in the same time period.	N/A
16	Hegel et. al (1989) USA	Behavioral intervention for chest pain with hyperventilation syndrome	Case study(A/B design)	3	Behavioural observations of breathing Symptom self-report	9 x 1-hour sessions over the course of seven to nine weeks.	Hospital cardiac clinic	Doctoral level graduate students in clinical psychology	Decrease in the intensity and frequency of chest pain episodes and in the frequency of shortness of breath episodes in all participants (n=3). Maintenance at 1-year follow-up was seen in two participants.	Participants (n=3) had minimum of 3 visits p/a prior to intervention . Post intervention : 0 visits p/a
17	Esler (2001) USA	CBT for chest pain	Quasi-experimental study	59 participants Two groups: Brief CBT intervention group (n=29) Treatment as usual group (n=30)	Chest pain frequency and severity (Chest pain interview) Anxiety Sensitivity Index (ASI) Brief Symptom Inventory (BSI) Cardiac Anxiety Questionnaire (CAQ);	1 x 60 minute CBT session.	Cardiac inpatient unit	Cardiac nurse	CBT group showed more effectiveness: decrease in chest pain episodes, anxiety sensitivity, and fear of cardiac symptoms at 1- and 3-month follow-up (p=0.02). Scores on measures of chest pain severity, cardiac-related avoidance or attention, quality of life, or general psychological distress showed no difference.	N/A
18	Tyrer et al. (2017) UK	CBT for chest pain	RCT	68 participants Two groups: CBT-HA group: 34 Standard care group: 34	Health Anxiety Inventory (HAI) Hospital Anxiety and Depression Scale (HADS) No. of attendances at A&E Health service costs	4-10 sessions of CBT	Cardiology clinics	Nurses and psychologists	Groups did not show statistical difference on any outcome measures at 6-months or 12-months follow-up, Those receiving CBT-CP had 2-3 times fewer hospital bed days, outpatient appointments, and ED attendances than standard care. Total costs per patient: £1496.49 lower (non-significant).	CBT group had less than half as many outpatient appointments and A&E attendances as those in the standard care group (over 12 months).
19	Lessard et al. (2012) Canada	Psychological interventionsfor panic disorder in chest pain	Quasi-experimental study	58 participants Three groups: Intervention group 1-session PMI (n=24) Intervention group: 7-session CBT (n=19) Control usual care (n=15)	PD Severity score on Anxiety Disorder Interview Schedule for DSM-IV (ADIS-IV) Body Sensations Questionnaire (BSQ) Agoraphobic Cognitions Questionnaire (ACQ) Panic and Agoraphobia Scale Anxiety Sensitivity Index (ASI) Cardiac Anxiety Questionnaire (CAQ)	PMI: 1 x 2 hour session panic management intervention CBT: 7 x 1 hour biweekly CBT session	ED	Psychologist	Panic disorder severity reduced signficantly post interventions when compared to control (p =.05). Neither intervention was superior.	N/A
20	Pelland et al. (2011) Canada	CBT or drug intervention for for panic disorder in chest pain	Quasi-experimental cohort study	47 participants. Three groups: Intervention group drug treatment (n=13) Intervention group: Brief CBT (n=19) Control usual care (n=15)	PS Severity score on Anxiety Disorder Interview Schedule for DSM-IV (ADIS-IV) Agoraphobic Cognitions Questionnaire (ACQ) Anxiety Sensitivity Index (ASI) Panic and Agoraphobia Scale (PAS) Beck Depression Inventory II (BDI) Cardiac Anxiety Questionnaire (CAQ)	Drug group: Generic paroxetine for 6 months, with regular medical follow-ups. CBT: 7 x 1 hour biweekly CBT session	ED	Psychologist	Significant reductions of PD severity seen in both intervention groups (p= .012). Other improvements were reduced frequency of panic attacks (p= .048), and reduced depression (p= .027).	N/A
21	Marchand et al. (2012) Canada *(follow-up study of Lessard (2012) and Pelland (2011))*	Panic in chest pain (follow-up)	Quasi-experimental study	71 participants Four groups: Pharmacotherapy group (n=13) CBT group (n=19) One-session panic management group (n=24) Supportive care as usual (n=15)	PD Severity score on Anxiety Disorder Interview Schedule for DSM-IV (ADIS-IV) Panic and Agoraphobia Scale (PAS) Agoraphobic Cognitions Questionnaire (ACQ) Anxiety Sensitivity Index (ASI) Body Sensations Questionnaire (BSQ) Spielberger State–Trait Anxiety Inventory (STAI) Beck Depression Inventory-Revised (BDI-II) McGill Pain Questionnaire (MPQ) Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)	7 x 1-h sessions of CBT using manualised approach 1 x 2 hour session of Panic Management CBT using a manualised approach	ED	CBT: Clinical Psychologist or Emergency physician (pharmacotherapy group)	PD severity improved post-treatment over time (p<.001) but there was not a significant difference between conditions (p=.095). Interventions more effective for severity of PD severity compared to usual care. Patients improved in all conditions in other measures, which were maintained at 1-year follow-up.	N/A

Study ID	Author & Year	Intervention type	Study Design	Sample	Key measures	Intervention	Delivery setting	Delivery personnel	Results	Frequent attendance impact
Clinical Presentation: Other - 'Medically Unexplained' Symptoms, Health Anxiety, Health Behaviour Change										
22	Katz et al. (2017) USA	Health behaviour change intervention in chest unit	RCT	140 participants Two groups Full intervention: n=70 Partial intervention:n=70	Various measures of health beliefs, behaviours & self-efficacy Health Motivation Assessment Inventory subscale (HMAI) Measures of stages of change for diet, exercise, smoking cessation. Cardiovascular risk behaviours rapid food screening survey Physical Activity Recall scale (PAR) Smoking behaviours	Maximum counselling 1 x 1 hour counselling + handout 2 x 30 minute follow up session 1 x follow-up phone call Minimal counselling Brief counseling (<5 minutes) + handout	Chest pain observation unit (CPOU) of an academic ED	Health Educator	The groups showed no signficant differences in measures of cardiovascular health beliefs, readiness to change, or CRF-related behaviors at follow-up.	N/A
23	Abbass et. al. (2009) Canada	Psychotherapy in medically unexplained pain symptoms	Pre-post intervention	50 participants	ED usage data Brief Symptom Inventory (BSI)	All patients were assessed and then attended a psychodiagnostic and evaluative interview. Some patients then had additional sessions (2 sessions (n=15); more than 2 sessions (n=15)).	ED quiet rooms or in hospital	Emergency practitioner	Significant improvements seen in >2 sessions (p< 0.01) on the somatisation subscale (p=0.02) and on the BSI global rating scale.	69% (3.2, SD 6.4) ED visit per patient reduction (p < 0.001)
24	Daniels & Sheils (2017) UK	CBT for Health Anxiety in Addison's Disease	Case study (A/B design)	1 participant	Health Anxiety Inventory (HAI) Patient Health Questionnaire (PHQ-9) Generalized Anxiety Disorder (GAD-7) ED usage data	12 x 1 hour CBT sessions	Clinic attached to an acute hospital ED	Clinical Psychologist	Reliable, clinical change seen across all measures, pre to post.	Pre= 6 visits p/a; Post=0 visits p/a

Analysis

The results are presented according to the study aims: delivery location; delivery personnel; intervention duration; intervention type, quality and efficacy; impact on frequent attendance, and acceptability and satisfaction ratings. Implications for practice are discussed in a later section. Follow-up studies are not considered in this section to avoid duplication (Des Groseilliers et al., 2013; Marchand et al., 2012).

Delivery location. Sixteen out of 22 studies were started and completed within the ED (including three postal/home-based interventions); 6/22 were completed within the hospital (e.g. clinic or ward). In terms of the types of interventions completed within the ED itself, this ranged from very brief bedside interventions to therapeutic sessions lasting up to 2 hours. Other hospital-based locations for intervention delivery included observation units, cardiac clinics, cardiac wards, surgical wards and clinical psychology outpatient departments.

Intervention delivery personnel. In 15/22 studies, intervention delivery personnel were a clinical psychologist, psychologist or other therapist. Other delivery personnel included: social worker, nurse, researcher (profession not specified), clinician (profession not specified), psychiatric professional and health educator (7/22 studies).

Intervention duration. The number of contact sessions required with intervention delivery personnel (excluding the postal interventions (n=2)) were: 9/20 studies: 1 session; 10/20 studies: ≥2 sessions. One out of 20 studies used technology to enhance normal care so this metric is not applicable. Individual session duration varied from 10 minutes to 120 minutes, with a modal duration of 1 hour. As an indication, in the panic/NCCP group, the mean duration of interventions was 3.6 hours (range: 0.5 to 9 hours) indicating that although some interventions could be completed within the ED, others would be completed post-discharge.

Intervention type, quality and efficacy: In terms of theoretical underpinning, 20/22 studies could be described as having a cognitive and/or behavioural component; 1/22 studies used a counselling approach to improve motivation to change and problem solving skills, and 1/22 studies had a psychodynamic underpinning.

Interventions grouped by clinical presentation.

Trauma/PTSD prevention group (11 studies). Three studies used a self-help approach. One study used a writing self-help intervention which was not effective (Bugg et al., 2009) and two studies used a psychoeducational/self-help brochure intervention which were also not effective (Scholes, Turpin, & Mason, 2007; Turpin et al., 2005). These studies all used a control group, but were of mixed quality on the assessment of bias.

Two studies used a CBT approach to prevent PTSD, and both interventions were effective. Wu and Cheung (2006) offered CBT to patients showing a moderate level of distress (IES-R) following a motoring accident, with a comparison group receiving self-help guidance. The results showed that the CBT intervention had positive impact on psychological symptoms at 6-month follow-up (HADS-A: p=0.02; HADS-D: p=0.01) but there was no difference in IES-R score between the groups. Methodological limitations included a lack of a non-treatment control and the study was underpowered which limits generalisability. Brunet et al. (2013) used a 2-session CBT intervention which found a modest effect (d=0.39) when the improvement observed in the control participants was controlled for. A strength of this study was the use of a no-intervention control. A related 2-year follow-up study (Des Groseilliers et al., 2013) - which included 70% of the original sample - found that the intervention was effective compared to controls (p=0.008) suggesting that this brief ED-based intervention is effective for preventing PTSD. A limitation is that there may be a sampling bias as 30% of the original sample did not participate at follow-up.

Three studies used exposure for PTSD-prevention. A 1-session exposure intervention (n=1) was effective despite displaying risk factors, participant did not display symptom worsening or develop PTSD (Post et al., 2017). However case study results must be interpreted with caution and are not generalisable. An initial pilot study showed promise using a 3 x 1 hour psychoeducation and exposure intervention (Rothbaum et al., 2008) however this was limited by a small n (n=10). The larger study (n=137) which followed (Rothbaum et al., 2012) showed effectiveness in preventing PTSD at 1 and 3-month follow up (1 month: p=0.004; 3-month: p=0.05) however the study was underpowered and there is a risk of type II error.

Finally, 2 studies used technology-enabled PTSD prevention intervention. One study was a proof of concept trial of a very brief intervention where patients played Tetris to prevent intrusive images (Iyadurai et al., 2017). At 1-week follow-up,

intervention participants reported less distress from intrusion symptoms than controls (d=0.54). The second study used technology to enhance usual care over 6 months (Zatzick et al., 2015). This intervention showed modest but non-significant symptom reductions (p=0.055) and the PTSD intervention effect was greatest at the 3-month (d= 0.35, p=0.044) and 6-month (d= 0.38, p=0.044) time points. This is an exploratory pilot study and the results support further research in this area.

As a group, these results indicate that offering interventions within the ED following trauma for PTSD-prevention is feasible and there is some evidence of effectiveness. The self-help interventions were not effective, but CBT showed effectiveness for psychological symptoms following trauma.

Panic/non-cardiac chest pain group (10 studies). This group of studies used a cognitive and/or behavioural approach for panic/NCCP related symptoms. One study compared treatment as usual (TAU) to a CBT intervention for patients with NCCP who are also diagnosed with depression in panic (van Beek et al., 2013). Using an intent-to-treat analysis at 6-month follow-up, the results showed that CBT was superior to TAU in reducing disease severity as assessed with the CGI ($p<0.001$). Positive effects were also seen on the HAM-D ($p<0.001$), HADS-A ($p<0.001$) and STAI-T ($p<0.001$). However significant differences between groups were not seen on the HADS-D, STAI-T, and FQ. The study has some methodological limitations including a high attrition of 34% after allocation.

Dyckman, Rosenbaum, Hartmeyer, and Walter (1999) reported an intervention for panic using either TAU and a psychiatric referral, and either a brochure or brief contact with an educator from the psychiatric department or ED personnel (n=354). The study does not report on the intervention's effectiveness, only the impact on ED utilisation. ED usage decreased in the brief contact condition a change which was statistically significant (p=0.0017) in comparison to the brochure condition. However it was not statistically signficant when compared with the historical control group (p=0.0672). An interesting finding was that ED use increased among patients given brochure only (discussed below). This study had a high risk of bias.

One paper presented a series of case studies (n=3) using a behavioural approach of breathing and relaxation for hyperventilation in chest pain (Hegel, Abel, Etscheidt, Cohen-Cole, & Wilmer, 1989). The intervention was effective and the effects were maintained at 1-year follow-up but no measure of significance is

provided. As case study results are not generalisable these results must be interpreted with caution.

One RCT study used CBT for health anxiety to treat chest pain in the cardiac clinic comparison to standard care (Tyrer et al., 2017). No significant group differences were found on any outcome measures at either 6 months or 12 months although there was a positive impact on ED attendance (discussed below). A limitation was that the study was under-powered. The paper does not explore the theoretical rationale or evidence to support intervention and it is possible that a different intervention might have been more appropriate.

Six papers (including one follow-up study) described using a CBT intervention to target panic symptoms. Two related papers covered four interventions. One study compared a one session panic management intervention with a 7-hour bi-weekly CBT intervention (Lessard et al., 2011). Another compared the same 7-session CBT intervention with medication (Pelland et al., 2011). These papers appear to describe the same CBT intervention with the same sample, although the later paper (Lessard et al., 2011) does not reference the earlier study (Pelland et al., 2011). A one-year follow-up study (Marchand et al., 2012) found efficacy across all of the interventions included in these papers: when compared with usual care, PD severity improved after treatment over time ($p<0.001$) with no significant difference between conditions ($p=.095$). However, these studies were assessed as having a high risk of bias.

Taken together, these results suggest that it is feasible to initiate psychological intervention for panic/NCCP in the ED and there is some evidence that these interventions are effective in reducing physiological and psychological symptoms. However, there were issues with the quality of the studies and the risk of bias analysis indicates a high risk of bias across the group (Table 1).

Other clinical presentations (3 studies). A study which aimed to support cardiac patients to moved towards a healthier lifestyle was conducted where patients received either very brief or extended behaviour-change counselling (Katz et al., 2017). The results did not show significant differences between treatment arms in longitudinal follow-up, however when the results of both treatment arms were combined patients showed significant differences on cardiac risk factor behaviour-change at follow-up ($p<0.0001$). However, the lack of a control group makes it difficult to conclude that this was due to the intervention, and it may have

been a response to the cardiac event.

Fifty patients with 'medically unexplained' symptoms including chest pain, headache, shortness of breath and abdominal pain received a short-term dynamic psychotherapy intervention with a minimum of 1 session (Abbass, Campbell, Magee, & Tarzwell, 2009). Improvements were seen on the self-reported Brief Symptom Inventory (BSI) ($p<0.01$) and also in terms of ED usage (discussed below). However this study had a high risk of bias and limitations included a lack of a comparison or control group and participant selection bias. Another study used CBT to reduce health anxiety in Addison's disease (Daniels & Sheils, 2017). The intervention was effective and anxiety symptoms reduced to a sub-clinical level and it also reported amelioration of ED usage (described below). However as this is a case study the results are not easily generalisable and also there was no pre-intervention baseline for comparison.

This group of three unrelated studies provides evidence of the feasibility of working psychologically with patients within the ED with three unrelated physical health problems. One study showed that it is feasible to deliver brief health behaviour change intervention in the ED (Katz et al., 2017) although the study was not effective. A brief emotion-focused intervention was effective in 'medically unexplained' symptoms (Abbass et al., 2009) and a longer-term piece of work was effective for health anxiety in Addison's disease (Daniels & Sheils, 2017). These results extend the evidence-base for the feasibility of delivering effective psychological intervention in the ED and suggest other potential clinical presentations that might be suitable for psychological intervention within the ED.

Impact on frequent attendance. Five out of 24 studies provided analysis of the intervention's impact on frequent attendance. Four of these interventions were cognitive and/or behavioural in orientation and one was psychodynamic. One study of two brief interventions for PD in the ED (educational brochure or one brief face-to-face intervention) found that patients who received this brief contact in the ED had a reduction in ED usage which was statistically significant (Tyrer et al., 2017). Patients in both groups were more likely to access psychiatric help for their PD upon discharge, when compared with the historical control. Increased ED attendance was seen in those patients who only received a brochure without a brief contact indicating that providing written material alone may not be helpful.

In the context of NCCP, another study (Tyrer et al., 2017) used a CBT

intervention (N=68, number of sessions: mean = 5.72, range: 4-10) showing that the CBT group participants had fewer ED visits compared to a standard care group in the 12 months following the intervention (standard care: mean 3.36 (SD 9.36)). In a study of patients with 'medically unexplained' pain (Abbass et al., 2009) including chest pain, abdominal pain or headache, patients (n=50) were given an emotion-focussed assessment and treatment intervention. Pre-post ED utilisation was measured which showed a 69% decrease (pre: mean 3.2, SD 6.4; post: 1.4, SD 2.7, $p<0.001$). Hegel et al. (1989) reported case studies of a breathing and relaxation intervention for hyperventilation in chest pain reported that prior to the intervention all participants (n=3) had attended the ED on at least three occasions in the year preceding and this reduced to 0 attendances in the year following intervention.

Finally, a case study (n=1) using CBT for health anxiety in a patient with Addison's disease (Daniels & Sheils, 2017) found that ED visits reduced from 6 visits in 12-months pre-intervention, to 0 visits in 12-months following treatment.

Five studies out of 24 studies reported the impact on ED attendance and in all cases ED utilisation decreased or stopped following the intervention.

Acceptability and patient satisfaction. All studies were reviewed to assess participant take-up rate following screening for eligibility. Results are presented in the table below for 15/22 studies (excluding the two follow-up studies). Four studies did not contain this information (Study IDs: 3, 8, 13,15) and three studies were case studies (Study IDs: 10, 16, 24). Take-up rates following eligibility screening were: ≤20%= 2 studies; 0-50% = 4 studies; 51-100% = 18 studies.

Table 4

Intervention take-up rates following eligibility assessment

ID/Author	Eligble to participate	Consented	Declined	% Accepted
9.Rothbaum (2008)	1361	140	1221	10%
6. Turpin (2005)	2818	291	2527	10%
5. Scholes (2007)	1934	411	1523	21%
18. Tyrer (2017)	108	40	106	37%
19. Lessard (2012)	113	58	55	51%
4. Iyadurai (2018)	140	73	67	52%
22. Katz (2017)	225	140	85	62%
17. Esler (2001)	94	59	35	63%
1. Bugg (2009)	148	107	41	72%
7.Wu (2014)	81	60	21	74%
20. Pelland (2011)	135	105	30	78%
12. van Beek (2013)	136	113	23	83%
11. Zatzick (2015)	287	247	40	86%
14. Nuthall (2007)	31	27	4	87%
2. Brunet (2013)	90	83	7	92%

Four studies had take-up rates below 50%: self-help following injury (n=2), exposure to prevent PTSD (n=1) and a CBT non-cardiac chest pain (n=1).

Five studies measured patient satisfaction ratings for their interventions with all reported positive feedback. The results are show in Table 3 below. This suggests that patients were supportive of receiving psychological interventions in the ED.

Table 3.

Patient satisfaction rating feedback

Study ID/Author	Subjective satisfaction rating (Quantitative results)
1. Bugg (2009)	Writing intervention group (n=31) rated usefulness of the task, scale of 1–5 (1=not at all useful, 5=extremely useful). All participants found writing useful, with 71% rating it as very or extremely useful. The mean rating of usefulness was 3.97 (SD 1.05).
4. Iyadurai (2018)	Tetris intervention. A 13-item questionnaire used, ratings of how easy, helpful and distressing/burdensome participants found playing Tetris on a scale from 1 (not at all) to 9 (extremely). Feedback ratings indicated that participants in the intervention condition found playing Tetris very easy (median = 7), very helpful (median = 7) and minimally distressing/burdensome (median = 1)
5. Scholes (2007)	Self-help intervention. Intervention participants rated sections of the self-help booklet on a scale of 1 (not useful) to 5 (extremely useful). Out of 60 completers, 52 rated the section on psychological sequelae, mean 3.60 (SD 0.87), with 94.23% rating it 3 or above and 51.92% rating it 'very' or 'extremely' useful. Fifty participants rated the section on coping strategies, resulting in a mean rating of 3.70 (SD 0.89); 94% rated it 3 or above, with 60% rating it 'very' or 'extremely' useful.
6. Turpin (2005)	Self-help intervention. 75 approached, 68 completed. Participants rated the usefulness of the booklet on a scale of 0 (not useful) to 5 (very useful), mean score: 2.98 (median=3, mode=4, range=5). Overall, 66% deemed the booklet useful.
23. Abbass (2009)	Dynamic psychotherapy intervention. Feedback requested from a sample over a 1-month period. 14 approached, 1 declined. Overall satisfaction rated as 7.4 out of 10 (SD 2.1, range 4–10) = between "satisfied" and "very satisfied".

Some studies also reported significant attrition rates but reasons for attrition were not fully explored and it is unclear whether this is linked to the intervention location.

Discussion

This literature review aimed to provide a systematic understanding of the effectiveness of hospital-based psychological interventions that were initiated in the ED. It was intended that these results could identify the scope of the available evidence, including the types of clinical presentations being treated, and the nature and effectiveness of the interventions in order that the results could inform clinical practice and service development. Results show that the evidence-base for psychological interventions in the ED can be broadly divided into three groups

based on clinical presentation which are panic/NCCP and trauma/PTSD-prevention, and there was a third group of miscellaneous studies representing emerging evidence in other areas: health anxiety in Addison's disease (Daniels & Sheils, 2017), behaviour-change in cardiac settings (Katz et al., 2017) and dynamic psychotherapy in 'medically unexplained' symptoms (Abbass et al., 2009).

The majority of the studies (20/22 studies) were underpinned by having a cognitive and/or behavioural approach and in 15/22 studies delivery personnel were a psychologist or therapist, suggesting that it may be important to have appropriately trained and supervised practitioners available in the ED setting. Linked to this, although some very brief interventions were used, patients also benefitted from longer term interventions (intervention duration range: 10 minutes to 9 hours). This suggests that the caseload of these practitioners could be comprised of both very brief bedside interventions and longer interventions delivered on an outpatient basis.

There was considerable heterogeneity within the studies making it difficult to make a meaningful statement about overall effectiveness, for example, studies had different foci, measures, follow-up periods. As an indication, within the trauma/PTSD-prevention group (11 studies) 9 studies reported at least one statistically significant result. In the panic/NCCP group (9 studies), 7 studies reported at least one statistically significant result, 1 study had positive results but clinically significant change was not calculated (Hegel et al., 1989) and 1 study did not report symptom impact (Dyckman et al., 1999) as it focused on the impact on repeat attendance. In the miscellaneous group (3 studies), two studies reported significant results (Abbass et al., 2009; Katz et al., 2017) and the third study which was a case study reported clinically significant change (Daniels & Sheils, 2017).

All five studies reported a reduction or cessation of repeat attendance following the intervention, indicating that offering psychological interventions within the ED could reduce inappropriate attendance. It is important to note that in two of these studies which reported a reduction, the authors did not record whether the ED visits were for the same or different clinical presentations. Offering appropriate psychological intervention to those who attend frequently is recommended in best practice guidance (RCEM, 2017) and these results provide evidence of benefit of doing so.

The results suggest that it is feasible to initiate interventions in the ED as

patients participated in the studies and the satisfaction data, although limited, shows positive results suggesting that patients accepted psychological intervention in this setting. It is notable that all available patient satisfaction data for interventions (5 studies) were positive - even when interventions were ineffective. However in order to better understand the role of psychological intervention in the ED, further research is required to explain take-up and attrition rates as not all patients accepted the intervention and some patients dropped out. Explanations for this are unclear and it would be useful to conduct further research to explore whether this has any relationship to the intervention location.

There is significant heterogeneity within the studies for example in clinical problems, intervention type, intervention methods and measures used. Other limitations are that the studies are of mixed but predominately low quality – no studies were assessed as having a low risk of bias across the board and all studies had at least three categories rated as having a high risk of bias. Another limitation was that five studies did not use a control or comparison group.

Despite these limitations, psychologists working in physical health settings can use these results to inform the case for increasing psychological provision within the ED and hospital settings. The results can be used to raise awareness in physical health settings about the potential impact of increasing psychological support which could include benefits for patient satisfaction and reducing repeat attendance. However, the results suggest that in order for patients to accept psychological interventions in medical settings, or for further research to occur, the support of medical teams is likely to be important. Intervention take-up rate was below 50% in 4/15 studies and if psychological provision were to be accepted by patients, front line staff would be the key to promoting these services to patients. The authors of an RCT of CBT for non-cardiac chest pain (Tyrer et al., 2017) noted that cardiologists were reluctant to participate in the trial, an RCT which ultimately generated some promising findings. The study concluded that in order for psychological treatments to be accepted in the ED, a significant shift in thinking is required from both patients and clinicians (Tyrer et al., 2017).

It is also important to consider the context of ED service when considering the implications of these results for practice and service development. In England, the five ED clinical indicators are: unplanned re-attendance, total time in the ED, attendance without being seen, time to assessment and time to treatment. Offering psychological treatment could lengthen treatment duration but could also positive

affect measures of quality and satisfaction. The evidence suggests that there are complex reasons beyond treatment duration that explain increased waiting times (King's Fund, 2018) and addressing these factors is likely to far outweigh any impact on waiting times created by adding brief, clinically indicated psychological intervention.

Overall, the results show that it is feasible to deliver psychological interventions within the ED for a range of clinical presentations and longer psychological interventions can be initiated within the ED and completed post-discharge. The evidence from novel services such as *IAPT@Flinders* (Bastiampillai et al., 2014) and the *SAMUR-Protección Civil* (Bell, 2010) demonstrates how innovative service design can be used to meet psychological needs in emergency settings. The problems of increased ED usage, waiting times and unmet needs are complex and part of the solution may include innovative service re-design including offering evidence-based psychological provision.

Further research

The results indicate that further high quality evidence is needed to determine which psychological interventions to initiate within the ED. The results of this review indicated that the evidence-base is clustered around interventions for trauma/PTSD-prevention and non-cardiac chest pain. Almost 50% of ED attenders leave without any medical intervention (House of Commons briefing paper, 2018) and it is likely that a proportion of these patients (and of those who have received medical intervention) might benefit from psychological input, particularly for presentations where the evidence suggests a psychological component. Promising findings on the impact of psychological interventions on frequent attendance suggests the importance of capturing this information in research, along with a cost-benefit analysis. It would also be helpful to report whether repeat attendance is for the same or a different clinical problem, as this was not always stated in the studies. The results showed variable take-up (Table 4), and attrition which is evidenced in the reduced risk of bias score. This suggests that further research on the acceptability of psychological intervention in the ED by patients and clinicians would be useful.

Limitations

The broad term 'psychological intervention' was used in this review as it

which fitted with the aim of scoping out the evidence-base. Although this term is commonly used in research literature, evidence from a systematic review indicates that a more specific definition may be helpful in research (Hodges et al., 2011).

Not all studies reported the upper age inclusion criteria or the sample age range. To reduce bias, at full text review all studies which had initially been excluded on sample age were included for discussion. Age parameters were not set during database searches and a second check of the excluded abstracts indicated that none had been excluded on age, but this is a limitation. Future systematic reviews might omit the upper age exclusion criteria as the search results did not find studies which focussed on older adults in the ED. This is an interesting finding in itself, as given the higher proportion of people aged over 65 presenting to the ED and the evidence for their different needs, this may indicate an area for further research.

Part of the eligibility criteria was the interventions were either completed in the ED or in the hospital setting in order that the results might be useful for understanding feasibility of delivering interventions in this setting. However it is acknowledged that there will be other interventions which could be delivered in this setting but were not included in this review. For example, the Jerusalem Trauma Outreach and Prevention Study (Shalev et al., 2012) identified patients in the ED who were then offered psychological interventions such as cogntive therapy or prolonged exposure. The results showed that these treatments were effective for PTSD prevention in recent trauma survivors. However, this study was excluded from this review as the intervention was delivered outside of the hospital setting. As such, when considering whether to increase the psychological intervention offering in the ED it would be important to consider a wider group of studies than are discussed in this review.

Risk of bias was analysed using the Cochrane risk of bias tool which is designed for RCTs. As such studies were deemed to be low quality due to the nature of their design (e.g. case study) however another assessment tool may have provided a different perspective. Due to feasibility, the risk of bias analysis was not independently completed by two raters and an assessment of quality (e.g. GRADE) was not completed.

Conclusions

This review provides evidence supporting the feasibility, acceptability and effectiveness of offering psychological interventions within the ED. Increasing psychological provision could help to close the gap between patient expectations and unmet need, reduce frequent attendance and improve patients' psychological wellbeing. Further high quality research is required to understand the effectiveness and acceptability of psychological interventions in the ED.

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Chapter 2: Service Improvement Project

Service improvement project of a pilot Tier 2 weight management course, 'Balance'.

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Abstract

Background: This service improvement project is concerned with an NHS Tier 2 weight management course called “Balance”. This pilot group ran from September to December 2016 and consisted of 12 weekly sessions with follow-up data collected at 3 and 6 months. Balance included dietetic, psychological and behavioural elements, underpinned by cognitive behavioural theory and third wave approaches including acceptance and commitment therapy (ACT), compassion focused therapy (CFT) and mindfulness. Eleven clients with a BMI of 25 – 40 kg/m2 enrolled on the course and nine clients completed it. **Methods**: A mixed-methods design was utilised which included analysis of outcome measure (weight, eating choices, weight-related self-efficacy and mental health) and and focus group data (n=6), analysed using thematic analysis. **Results**: Non-parametric analyses using Wilcoxon signed-rank tests showed that the group mean weight decreased significantly (p = 0.030) by the end of Balance but this was not maintained at 3-month (p = 0.345) or 6-month (p = .086) follow-up. A small *n* limits interpretation. The qualitative results showed that participants valued the course ethos of choice, and welcomed learning new tools and techniques. **Conclusions:** Project recommendations included further aligning the course material to NICE guidelines whilst retaining the course ethos, monitoring ‘readiness to change’ during the course and providing additional post-course support to help participants maintain changes.

Key words: weight management; service improvement; primary care mental health

Background

Obesity, defined as having a body mass index (BMI) above 30kg/m2, is a complex problem affected by a range of factors including behaviour, genetics, environment and culture (Public Health England, 2017). It affects 26% of UK adults compared to 15% in 1993 (NHS Digital, 2018) and prevalence rates are suggested to vary by sex, age and socio-economic status (NHS Digital, 2018). The highest levels are seen in men age 45-74 and women aged 45-84, with 38% of women in more deprived areas experiencing obesity, compared to 20% of women in the most affluent areas (NHS Digital, 2018). Obesity is associated with increased health risks and health costs, with weight-related NHS costs predicted to reach £9.7 billion by 2050 (Public Health England, 2017). NHS weight management services are typically split into four tiers based on BMI however access to services is inconsistent

nationally (Public Health England, 2015). As an indication, a national survey of weight management commissioners (N=330) found that 20.6% of responders (n=68) reported that there were no Tier 2 or Tier 3 weight management services for children, young people or adults in their area (Public Health England, 2015), indicating a gap in service provision.

Designing effective weight management programmes

Programme components. NICE Guidelines (2014) recommend that weight management programmes are multi-component which is defined as addressing behaviour change, physical activity and diet. A synthesis review of the efficacy of longer-term, multi-component weight management interventions found that programmes with three components (e.g. diet, physical activity and behaviour change) were more effective than those with one or two components (Kirk, Penney, McHugh, & Sharma, 2012). PHE's National Mapping of Weight Management Services (2015) noted that 66% of Tier 2 services are described as multi-component (e.g. physical, behaviour change, dietary advice) which is in line with NICE guidelines (2014). However, PHE (2015) acknowledge that commissioners face commissioning barriers which include a lack of evidence for these programmes and lack of clear guidance on what to include within these programmes.

Theoretical underpinning. A synthesis review of systematic reviews of dietary and physical activity interventions found that including behaviour change techniques such as goal-setting and self-monitoring, increased intervention effectiveness, however, having an explicitly stated theoretical underpinning did not increase effectiveness (Greaves, 2011). Another synthesis review of lifestyle interventions (Kirk et al., 2012) concluded that behavioural approaches are effective and evidence indicates that adding cognitive behavioural therapy (CBT) can help to change dietary cognitions. Given this evidence, NICE guidelines (2014) recommend using behavioural techniques such as self-monitoring and goal setting.

Third wave approaches. Psychological difficulties such as weight-related stigma are thought to negatively impact weight management (Tomiyama, 2014).To address this, third wave approaches including acceptance and commitment therapy (ACT), mindfulness and compassion focussed therapy (CFT) are increasingly being used in weight-management interventions. ACT focuses on increasing distress-tolerance skills to bring actions in-line with values (Forman, 2015). Mindfulness aims to increase metacognitive awareness and raise awareness of automatic processes,

such as eating on auto-pilot, which can improve self-regulation (Daubenmier et al., 2016). CFT has targeted shame, self-directed hostility and self-criticism, and shown effectiveness in an eating disordered population (Goss & Allan, 2014). These approaches tackle difficulties including shame and self-criticism through self-compassion and decreasing emotional avoidance (Palmeira, Pinto-Gouveia, & Cunha, 2017). Evidence for effectiveness has been explored in a randomised controlled trial of an ACT, mindfulness and CFT based 10-week group intervention (n=73) called 'Kg-Free', which was compared with treatment as usual (TAU) of medical and nutritional advice (Palmeira et al., 2017). The intervention group saw statistically significant improvement across all variables including quality of life, healthy behaviours, reducing negative experiences and improving psychological functioning (medium to large effects). BMI reduced more in the intervention group than TAU with a small effect (d = 0.09). These results suggest that using third wave approaches may be helpful for handling negative weight-related experiences but significantly reduced BMI may not be seen in the short-term.

Improving 'Balance'

Balance is a psychology led, primary care Tier 2 service weight management intervention delivered by a primary care mental health service. A Clinical Health Psychologist designed the course and the 12 weekly sessions included dietetic, psychological and behavioural elements, underpinned by CBT, ACT, mindfulness and CFT. Balance was designed to follow a course called 'Get Ready for Change' (GRFC), which prepares clients for weight loss through change-based models and strategies. It was a joint initiative between the service and the Public Health commissioners. Inclusion criteria for attending Balance were BMI between 25-40 kg/m2; not attending another weight management programme; not meeting criteria for an eating disorder and completion of GRFC.

Aims

The aim of this project was to assess Balance's effectiveness and to make improvement recommendations to inform subsequent groups. Although the course was designed with reference to the evidence-base the group was a novel development without previous exploration of its efficacy. The service improvement project investigated two questions:

1. What impact did this group have on the outcome measures of: weight

change, weight-related self-efficacy, dietary choices and mental health?

2. What suggestions do group attendees have for improving Balance?

Method

Participants

Eleven clients started “Balance’ (9 females, 2 males) and one person dropped out at Week 6. An average of 9 sessions were attended per client with a range of 6 – 12 sessions (m = 9.1, SD = 1.97). BMI ranged from 26.7 to 39.6 (m =33.19) (n = 10), and ages ranged from 37 to 82 (m = 55.8) (n = 10).

Setting and ethics

The course ran from September to December 2016, with one follow-up session in March 2017. Follow-up data was also collected in June 2017. The project was registered with the relevant NHS Mental Health Trust as a service evaluation project (Ref: E2016.025) and received ethical approval from The University of Bath’s Psychology Ethics Committee (Ref: 16-218). An information sheet was given to group attendees and informed consent was obtained for participating in this project.

Design and procedure

A mixed-methods design was utilised which included analysis of outcome measure and focus group data.

Quantitative methods: A within subjects, repeated measures design was used. Group attendees were invited to complete weekly outcome measures during the course and at two follow-up points (3 months and 6 months later) which were analysed using Wilcoxon signed-rank tests.

Qualitative methods: All Balance attendees were invited to a focus group (including those who did not complete the course). A semi-structured interview protocol was developed in collaboration with the service, and previous research (Hindle & Carpenter, 2011; Metzgar, Preston, Miller, & Nickols-Richardson, 2015), discussion with the project’s commissioner, and the author’s review of Balance course material, informed the questions.

Analysis

Quantitative analysis. Wilcoxon signed-rank tests were used as the data did not meet assumptions for parametric tests. The author analysed the data using Excel and SPSS (Versions 23 and 24).

Qualitative analysis. The focus group was audio-recorded and the author analysed the data using thematic analysis (Braun & Clark, 2006). An independent analyst (Trainee Clinical Psychologist) also rated the coding to assess inter-coder reliability (Campbell, 2013). There was 80% agreement and other discrepancies were resolved. The analysis was completed from a realist standpoint as the aim of the research was to improve services, rather than to explore the meaning of experiences, or the broader social context. In line with guidance provided by Braun and Clarke (2006) the thematic analysis focused on the service improvement aspects of the data rather than producing a description of the entire data set as the conversation broadened out to discuss areas that were not under the direct influence of the service, such as social and environmental factors. A semantic approach was taken to identifying the themes, meaning that the themes were identified by considering the explicit meaning without deeper interpretation (Braun & Clarke, 2006).

NICE guidelines gap analysis. A gap analysis was conducted between the NICE guidelines PH53 Weight management: lifestyle services for overweight or obese adults (2014) and the Balance course content. The analysis compared the Balance course material to the suggested components of successful weight management interventions as reported in the guidelines. The results were used to inform the project recommendations.

Measures

The service chose and administered the outcome measures. These included the IAPT minimum data set (mental health measures) which were included due to a service requirement and were included in the analysis at the service's request.

Table 1

Summary of measures

Measure	Details	Collection Frequency
IAPT minimum data set: Patient Health Questionnaire PHQ-9,Generalised Anxiety Disorder questionnaire, GAD-7, phobias questionnaire, Work & Social Adjustment Scale.	PHQ-9 is a validated, 9-item measure of depressive symptoms (Kroenke, Spitzer, & Williams, 2001). It measures depressive symptoms over the past 2 weeks. Nine items are rated on a 0 to 3 scale. A total score of 10 or more indicates clinically significant depressive symptoms. The scale has excellent internal consistency (α = 0.89) and excellent test-retest reliability (r = 0.84). The clinical cut-off is a score of 10 or above. GAD-7 is a validated, 7-item questionnaire which measures symptoms of anxiety over the past 2 weeks (Spitzer, Kroenke, Williams, & Lowe, 2006). Items are rated on a 0-3 scale. The scale has excellent internal consistency (α = 0.92) and good test-retest reliability (r = 0.83). The clinical cut-off is a score of 8 or above.	Weekly during the course
Weight Efficacy Lifestyle questionnaire (WEL)	*A* validated, 20-item questionnaire which is used to measure changes in self-efficacy (M. M. Clark, Abrams, Niaura, Eaton, & Rossi, 1991). The scale measures the ability to resist or control eating in relation to five factors: Negative Emotions, Availability, Social Pressure, Physical Discomfort, and Positive Activities. Participants choose from a 10-point scale (0-9) with higher scores indicating greater confidence in being able to resist eating in those situations. The	At start and end of course, and at 6 month follow-up

	questionnaire can give subscale scores and overall self-efficacy scores. The scale is reported to have acceptable internal consistency and a stable 5-factor structure (M. M. Clark et al., 1991)	
UK Diabetes and Diet questionnaire (UK D&D)	*A* twenty-five item questionnaire which provides a quick assessment of an individual's diet. The scale is reported to have excellent test–retest reliability for the total score and for almost all the individual items (England, Thompson, Jago, Cooper, & Andrews, 2017). It has been validated for use with a White British population in clinical and non-clinical settings, which fits for the Balance group participants. Question responses are scored with a letter: As and Bs = Healthy dietary choices; Cs and Ds = Less healthy dietary choices Es and Fs = Unhealthy dietary choices. More E and F responses indicate an unhealthier diet. There are also three questions which relate to how much the individual wants to make changes to their diet and whether they think those changes are possible.	At start and end of course, and at 6 month follow-up
Weight and waist circumference measurements		At start and end of course, 3-month & 6 month follow up.
The Patient Experience Questionnaire (PEQ)	A standard IAPT questionnaire collecting quantitative and qualitative data.	Once, at end of course

Balance end of course feedback questionnaire.	A questionnaire designed by the service collecting quantitative and qualitative data.	Once, at end of course

Results

Nine participants provided complete course data (pre and post course). Data at three-month follow-up was collected from 5 participants, and at the six-month follow-up the same 9 participants also provided their data (self-report n=4; in-person weighing n=5).

Question 1 – Outcome measures

Weight change results

At the end of Balance (n=9) 6 clients had lost weight (range: 0.5% - 8.1%); 2 saw no change and 1 client gained weight (representing a 1% increase in body weight since the course started). A Wilcoxon signed-rank test (on pre and post Balance weight data (n=10)) based on positive ranks indicated that the group's mean weight decrease from pre-course to post-course was statistically significant (Z = -2.173, p = 0.030).

At the 3-month follow-up (n=5) 4 clients had lost weight (range: 1% – 11.4%) and 1 person gained weight (representing a 7% increase in body weight since the course started). Analysis was conducted on pre-course and 3-month follow up weight data, only using data from participants who provided data at this follow-up (n=5). A Wilcoxon signed-rank test based on positive ranks indicated that the group's mean weight decrease from pre-course to 3-month follow-up was not statistically significant (Z = -.944, p = 0.345).

At the 6-month follow-up (n=9), 7 clients had lost weight (range: 0.5% - 13.8%). One person had lost more than 10% of their starting weight, 2 clients had lost 5-10% and 4 clients had lost under 5% of their body weight. Two clients had gained 2-3% of their body weight. Analysis was conducted using data from participants who provided data at both time points. A Wilcoxon signed-rank test based on positive ranks indicated that the group's mean weight decrease from pre-course to 6-month follow-up was not statistically significant (Z = -1.718, p = .086).

Analysis was also conducted using pre-Balance and 6-month follow up weight data (excluding self-reported weights (n=5)). A Wilcoxon signed-rank test based on positive ranks indicated that the group's mean weight decrease from pre-course to 6-month follow up for this group was not statistically significant (Z = -.135, p = .893).

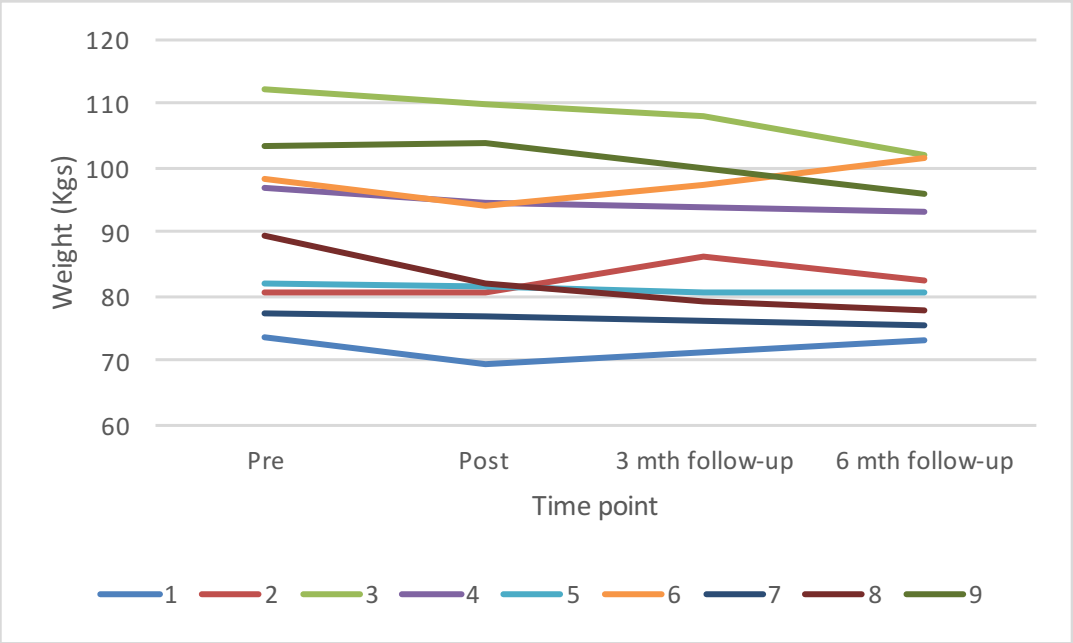


Figure 2. Weight change from pre-course to 6-month follow-up

Mental health results

One person had recorded a pre-group PHQ-9 score above clinical cut-off, which reduced from 11 (pre-course) to 4 (post-course). The table below shows group means scores, pre and post course:

Table 2

Pre and post group mean scores for the PHQ-9 and GAD-7

Measure	Pre-Balance	Post-Balance
PHQ-9	4.9	3.3
GAD-7	3.3	2.8

Analysis of the PHQ-9 data shows that 6 clients had a lower depression score after the course, 2 clients had a higher depression score after the course and 1 person's score remained the same. A Wilcoxon signed-rank test indicated that there was not a statistically significant decrease in group mean depression scores from pre-course to post-course (Z = -0.985, p = 0.325)

Analysis of the GAD-7 data shows that 3 clients had a lower anxiety score after the course, 3 clients had a higher anxiety score after the course and the level had not changed for 3 clients. A Wilcoxon signed-rank test indicated that there was a not statistically significant decrease in group mean anxiety scores from pre-course to post-course (Z = -0.108, p = 0.914).

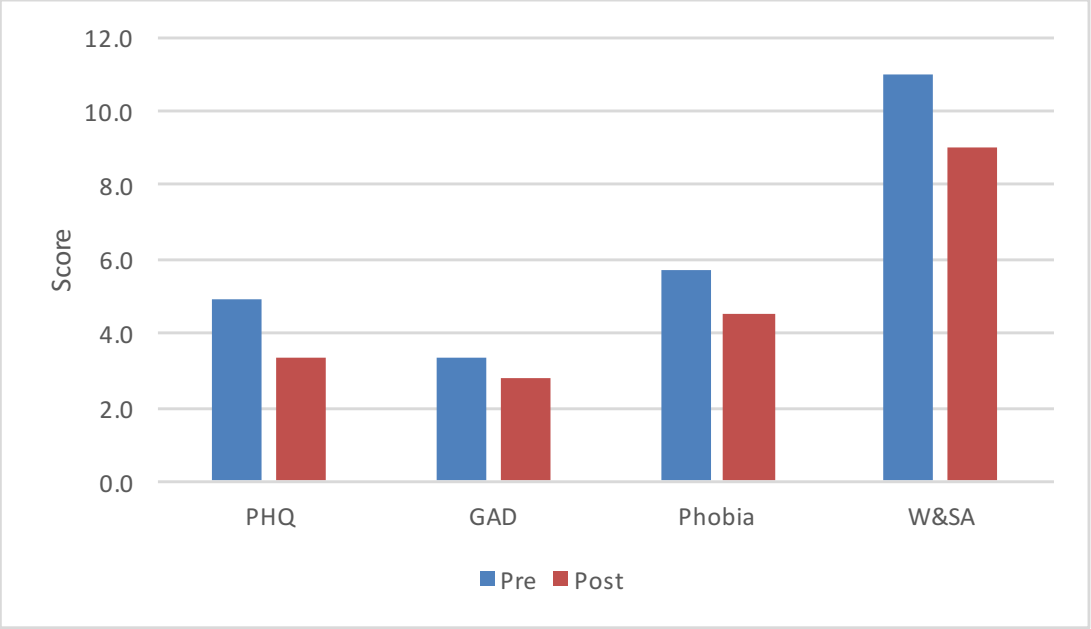


Figure 2. Mean scores pre and post group on tservice's mental health questionnaires (IAPT minimum data set).

Weight efficacy results

There was an increase of 34 points from pre-course to post-course in the mean total score on the Weight Efficacy Life-Style Questionnaire (WEL), suggesting an increase in weight-related self-efficacy and an increased self-rated ability to resist eating in certain situations.

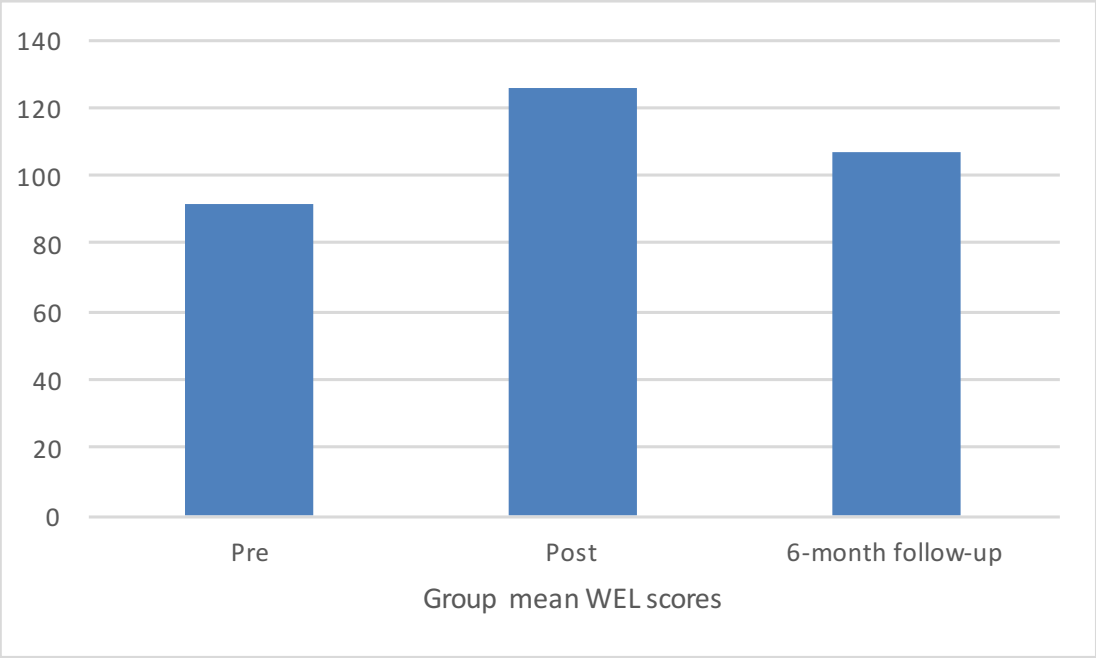


Figure 3. Group mean scores on WEL questionnaire – pre and post (n=9) and 6-month follow-up (n=5)

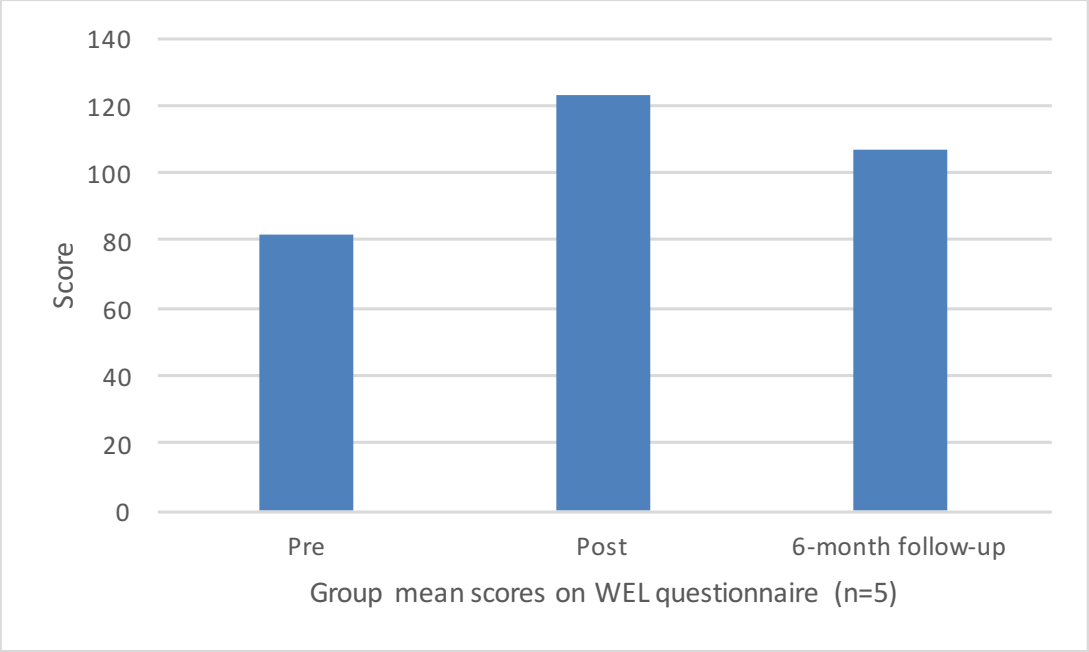


Figure 4. Group mean scores on the WEL questionnaire – pre and post (n=5) and 6-month follow-up (n=5)

The pre and post scores for all 5 subscales show a marked improvement in confidence. For this group the greatest difference was shown in the Social Pressure subscale; the average total scores changed from 17.9 to 25.8.

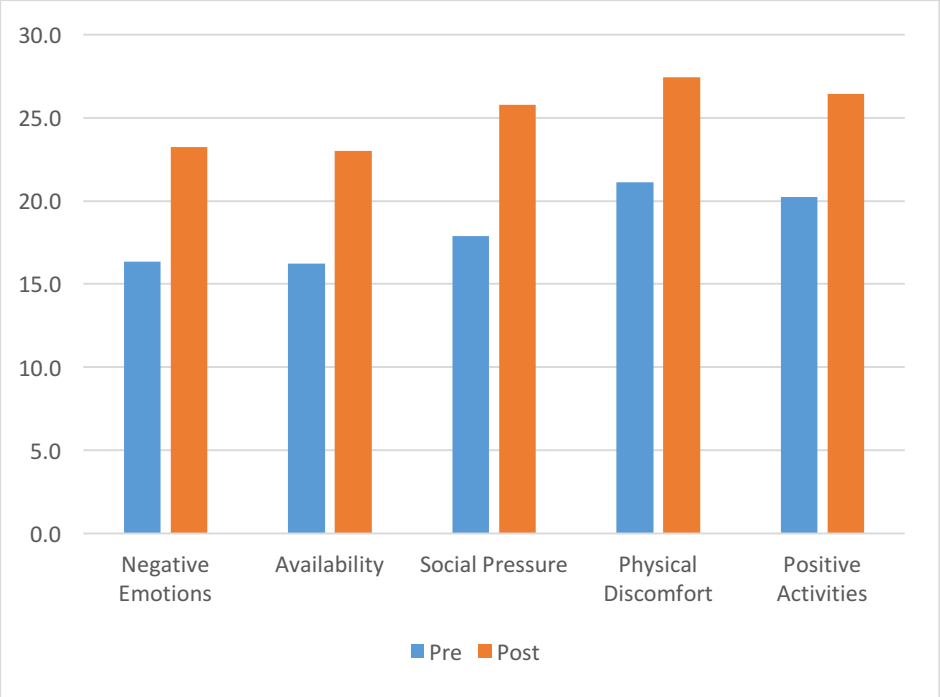


Figure 5. Group mean sub-scale scores on the WEL questionnaire – pre and post (n=9)

Dietary choices results

The UK Diabetes and Diet Questionnaire (UKDDQ) was used to assess change in dietary choices. Nine participants provided responses pre and post-course, and 5 participants responded at 6-month follow up. At the end of the Balance course, participants made fewer 'less healthy' (Cs and Ds) and 'unhealthy' food choices (Es and Fs) and they also made more 'healthy" food choices (As and Bs).

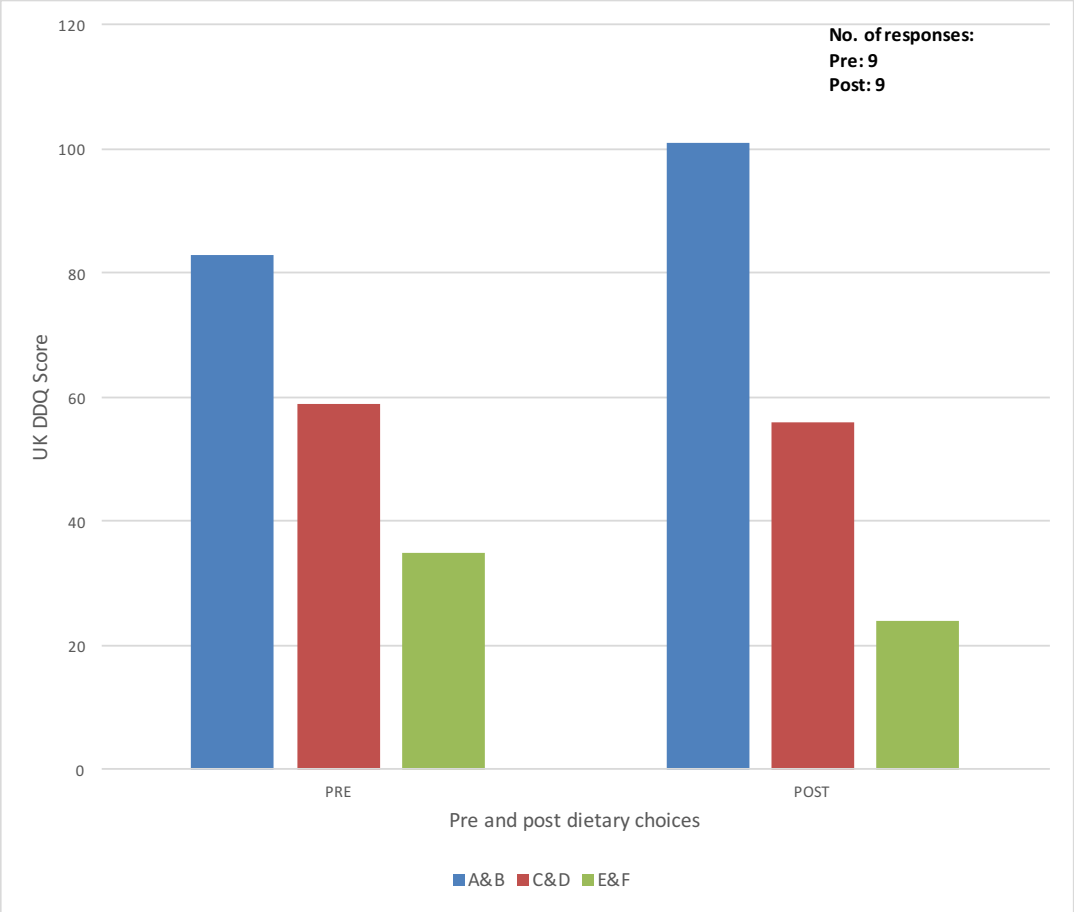


Figure 6. Group dietary choices pre and post (n=9) as measured on the UKDDQ

Five participants provided responses at the 6-month follow up. The graph below uses data from this group at 3 time points.

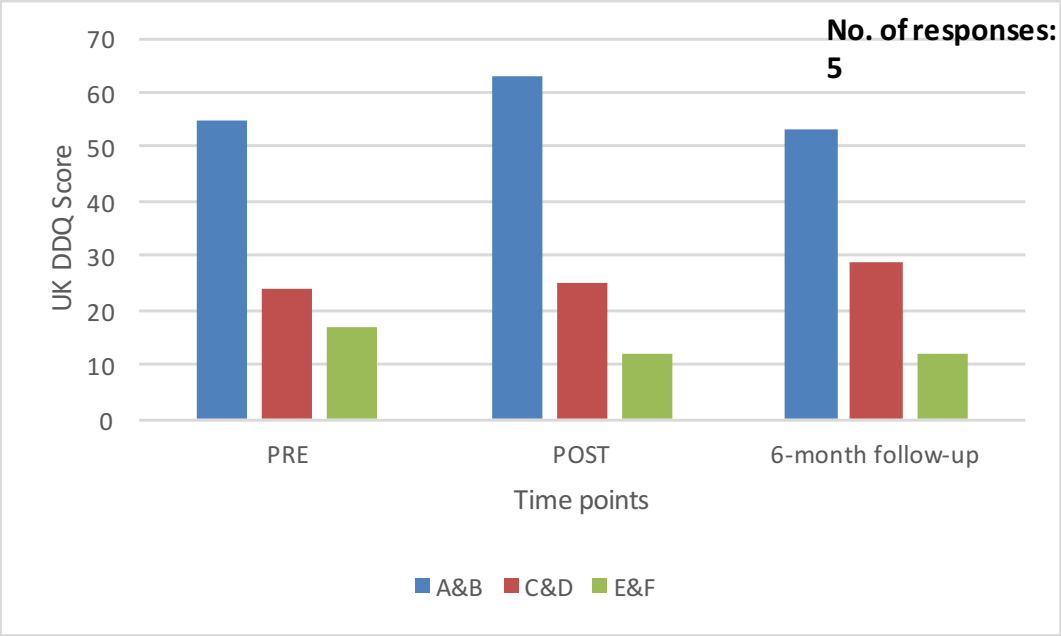
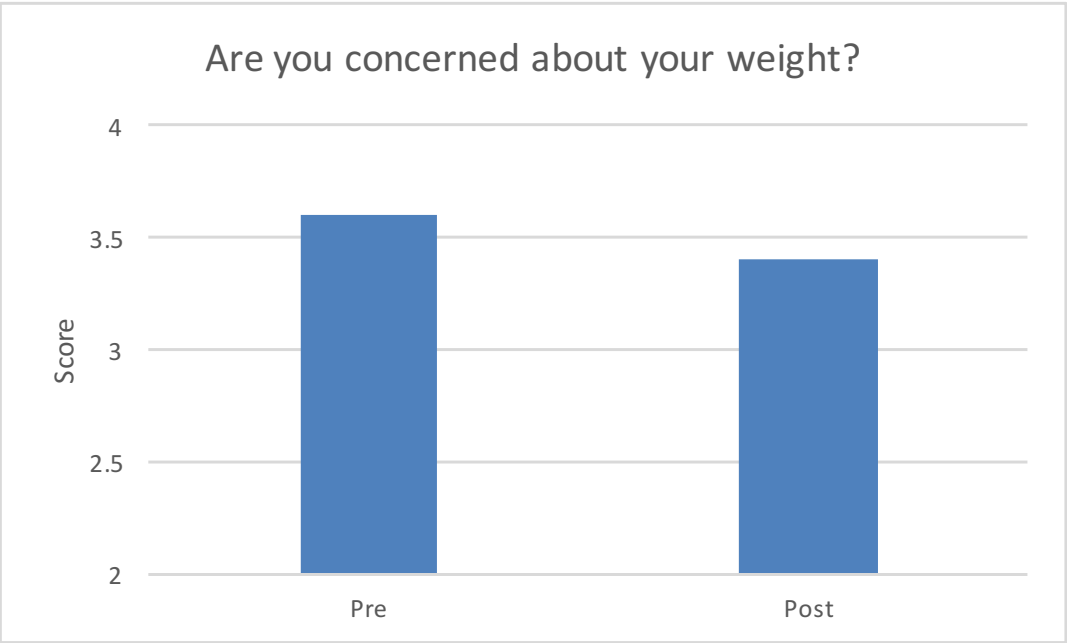


Figure 7. Group dietary choices at 3 time points (n=5) as measured on the UKDDQ

The questionnaire also asked three questions about weight concern, the importance of changing diet and confidence in changing diet. The following graphs show the change in score pre and post Balance (n=9). Results showed that as a group, service users were slightly less concerned about their weight at the end of Balance, and it was slightly less important for them to change their diet. However confidence that they could change their diet had slightly increased.



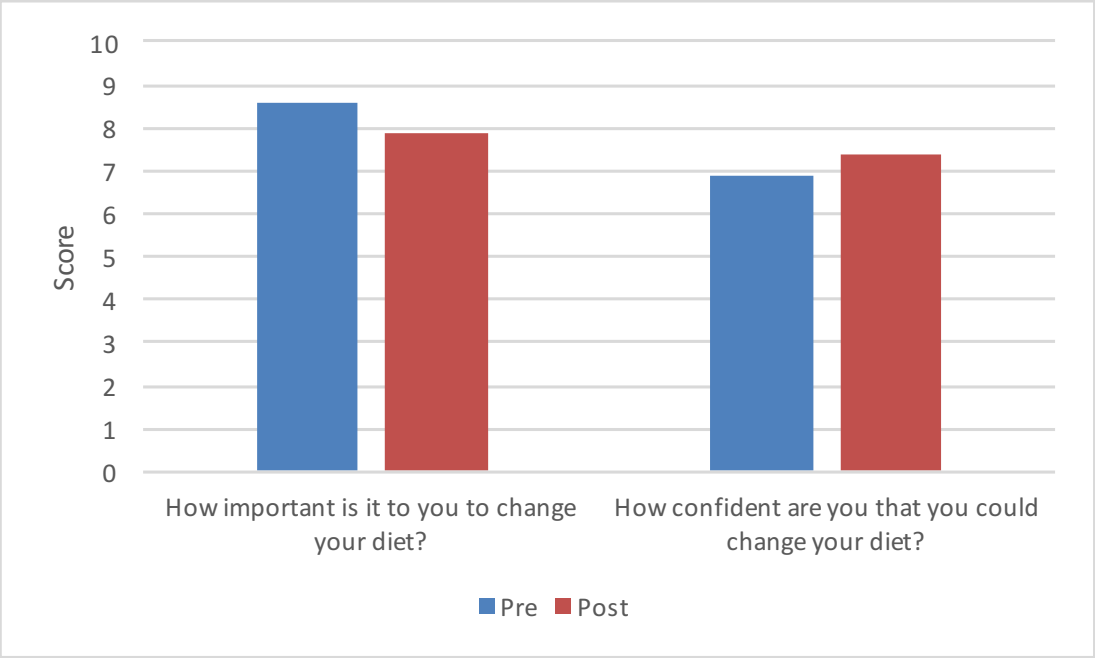
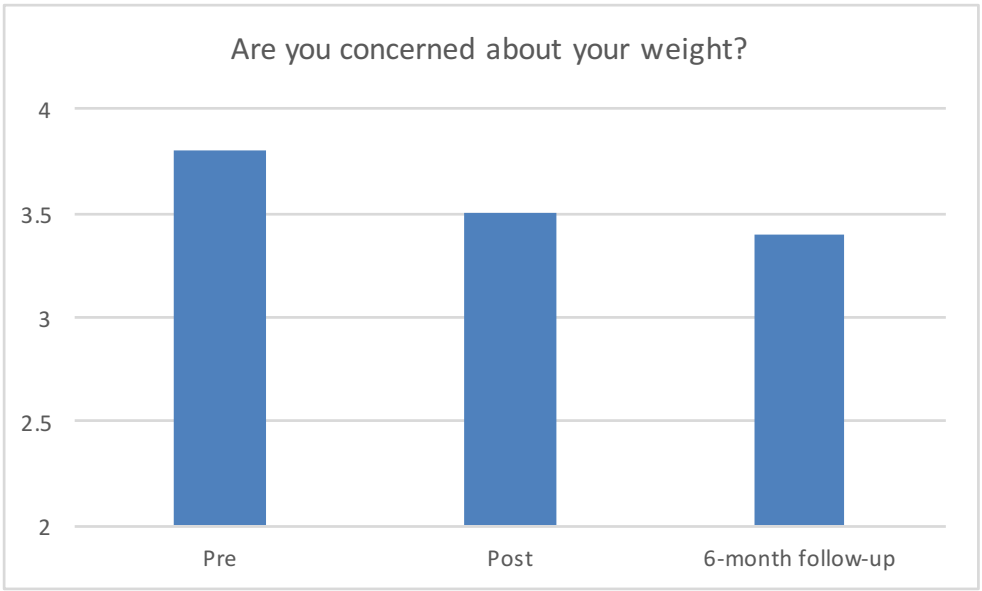


Figure 8. Group mean scores on questions 23 – 25 of the UKDDQ questionnaire – pre and post (n=9)

The UKDD questionnaire was also completed at the 6-month follow-up. The following graphs show the data from the 5 participants who completed the questionnaire at the 6-month follow-up.



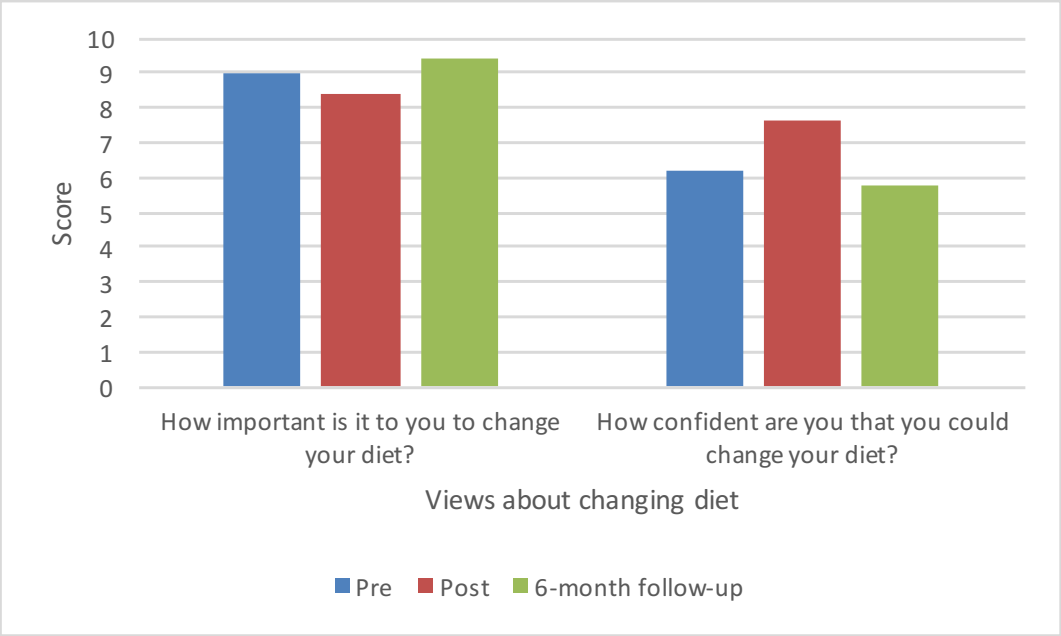


Figure 9. Group mean scores on questions 23 – 25 on UKDDQ – pre, post & 6-month follow up (n=5)

Responses given on the UKDDQ by this group (n=5) indicated that service users were slightly less concerned about their weight at the 6-mon follow-up point, compared to at the course end. At the end of Balance, confidence about changing one's diet had increased by the end of the course, which was also in line with an increase in weight-related self-efficacy shown seen the WEL at the end of Balance. However, at the 6-month follow-up, group mean confidence level on the UKDD and also on weight-related self-esteem (WEL) had decreased. This may suggest that the gains from the group faded over time, and that follow-up support might be beneficial – particularly as the group showed that the importance to them of making these changes had increased.

Question 2 - Focus group results

Six clients participated in the focus group (4 females, 2 males). Data analysis showed seven themes.

Theme 1: Gaining new knowledge and skills. Participants gained a new understanding of weight management through learning evidence-based information (including physiology, psychology, and nutrition) and new tools and techniques. This is grouped under two sub-themes. The science behind weight management captures the comments about the evidence-based course material,

including nutrition science, dieting and psychological understanding of weight management.

> "I personally found it very helpful to go deeper, not just about the food, but you know, what's behind the scenes so to speak, in each one of us, you know, the psychology of it, the understanding of it …" (P4)

> "I learned quite a lot about the scientific things happening in your body as well, so like the hormones that are involved with, and affect your eating." (P6)

Participants also talked about learning new tools and techniques during Balance. The tools included the Eat Well plate and techniques such as distraction and mindfulness. These were used during and after the course. Participants valued learning via visual and kinesthetic methods.

> "It was the mindfulness ... When they gave us that piece of chocolate … Making you actually look at it." (P2)

> "They opened my mind to distraction techniques. I'd not considered what that even was." (P3)

> "I'm quite a visual learner and what really helped me, was … seeing things visually, and that was seeing the balance of food and energy you take in … and you have to expel … and it was literally the balancing scales." (P5)

Theme 2: Valuing the course ethos. Participants valued Balance's philosophy, approach and long-term focus, and there were two sub-themes: positivity, hope and freedom captures the ideas that other weight management programmes are about denial, restriction, hopelessness and failure, but Balance is about freedom to choose, hopefulness and positivity.

> "I suppose where as you do a diet you're more restricted. With this, I like that I don't feel that restriction, because that knowledge has actually given me a freedom and better choices. I don't have to do what's written down in the dos and don'ts." (P4)

> "There's none of this sense of failure or hopelessness of, I just can't do this! I just cannot face doing this! You know, trudging on, which is what I've felt in diet groups." (P4)

> "The other thing about the difference between this and [*names commercial weight management group*] is it's our choice we've been given the tools … but if you go there, you're constantly saying "you can't have this, you can't have that". (P2)

The second sub-theme of 'long-term change' captures comments that Balance is not pitched as a short-term fix, but aims to bring about long-term change.

> "So there's a lot of difference. This is a totally different course to those courses that are out there that all really want you to go back and spend some more money when you put some weight on." (P2)

> "Well there was a couple of people every so often would say,*"well I'm not doing very well on my diet*"… and every time someone said that, they would respond with, "you're not on a diet" (P6)

Theme 3: Readiness for change. Some participants talked about their readiness for change and two out of six participants said that they were not ready to change when starting Balance, with one participant noting that they had moved back to the contemplation stage during the course. Narratives emphasised that even if the participant was not making changes at present, the course had given them the tools, knowledge and skills to be able to make changes in the future.

> "I knew when I was doing this course … I knew that I wasn't in the right frame of mind to be thinking about losing weight or any of those sorts of things, but what I used Balance for was a preparation" (P3)

> "I didn't do the course to lose weight primarily. I did the course to prepare myself with the knowledge that the course has given us, to do something different. (P4)

"And if it goes forward … you could do it again. You'd actually be able to go back and do it again." (P2)

Theme 4: Importance of group support. Participants valued the group support, both during and after the course including sharing ideas, learning from others and being inspired by other group members. This was done face-to-face at the group and through social media.

"We were able to discuss these sort of solutions as well, amongst us … They come up with like problems, but actually we came up, with answers to those problems. And we all came up with different answers because we've got different ways of life and stuff." (P6)

"That's how I felt I benefitted, by listening to everybody and how they were dealing with each situation which was known to me, I thought "oh yes, I know what they're talking about" and I thought "oh that's how they deal with it."" (P1)

Most participants expressed a desire for support after the course including continued contact with group members. There was also a desire for additional service provision, such as a regular meet-up group.

"P5: I want to know what happens to everybody!!
P2: You've got a good point there! Knowing what happens after.
P6: Meeting up reminds you, if you can re-discuss and re-visit these things. That for me would just again, be another step to really improve everything. I know there's financial implications of that"

Theme 5: Making changes. Most participants discussed the changes they had made during and after the group, which can be grouped into cognitive and behavioural changes. The cognitive changes participants reported included: noticing and challenging rules, particularly those developed in childhood; developing a new 'mindset' - including increased self-efficacy about weight management (change is possible and achievable); reduced 'all or nothing' thinking; regaining control; and increased confidence with handling relapses.

> “It completely changed that way I looked at things and it put me in that right state of mind to be able to move forward and to use everything that we were sent.” (P4)

> “I’ve got the mind-set to adjust.” (P4)

This theme also includes participant reports of personal reflection on course material and discussions which lead to changes in eating related cognitions or exercise behaviours.

> “It’s also changed our mind on things like … a lot of us were told when we were younger that we had to clear our plate. “ (P2)

Behavioural changes included eating (making wiser choices, changing meal patterns) and exercise (getting active, changing activity types).

> “But the other thing it did … was to look at exercise completely differently. I always think if you’re gonna do exercise you’ve gotta go to the gym, or you’ve gotta play some kind of sport … but …it’s not just about exercise but it’s about just keeping moving.” (P5)

Theme 6: Benefits beyond weight loss. Participants described additional and unexpected benefits from attending the course including improved mental health.

> “I think it makes you feel better. It makes a better sense of wellbeing. That’s the only way I can describe it.” (P2)

> “It’s changed my life ... It has. It’s completely changed my life … I quit my job and everything!... It’s changed my life. It’s changed my whole attitude” (P6)

> ”It’s changed the way I look on life. And I am now a happier person than I was before I started, without a doubt.” (P4)

Some participants also discussed developing and re-discovering hobbies and others talked about a renewed interest in cooking.

> "It's brought back something I like doing … actually going and buying fresh vegetables … and creating a meal, and just using the fresh fish, I'm loving that again!" (P4)

Theme 7: Conviction that the course needs to be shared with others. Some participants talked about the importance of sharing information from the course with other people. Some participants said that they were already sharing the course content with family and friends.

> "I've been going through some of this with my daughter…" (P4)

> "I've talked quite a lot about this with my little boy …" (P6)

Most participants emphasised that Balance should be shared more widely through extended service provision, particularly for younger people.

> "I want this to go out … My thing would be that [*names commercial weight management group*] will fall to the ground because everybody will know exactly what this course was about. And that for me would be my ultimate aim" (P2)

> "You need to do it younger. We need to do it from school upwards as well as out to the public. We need this to go into schools." (P2)

> "It would be so, so sad not to have all of this. You know, just filed away in a drawer somewhere not to be continued. There's too much here not to share." (P4)

Course feedback results

Group attendees completed the Balance end of course questionnaire to provide feedback. All Balance attendees rated the group as Excellent or Very Good, rated the course leaders as Excellent or Very Good and would recommend the course to a friend (n=11). Further information from this questionnaire is in Appendix E.

NICE guidelines gap analysis results

During the focus group no participants commented on formal self-monitoring. In order to determine whether this was a part of the Balance the course content was reviewed and was also compared with the NICE guidelines (2014), to inform the recommendations. The results showed that the Balance course content partially aligned with NICE guidelines (2014) but greater alignment could be achieved by: involving a physical activity instructor in course design/delivery; agreeing achievable weight loss goals with each client and increasing the level of self-monitoring. The analysis was used to inform the recommendations (Appendix F).

Discussion

The aim of this project was to determine whether the Balance pilot was an effective intervention and to make improvement recommendations based on the outcome measure data and focus group results. At the end of Balance, group mean weight loss was statistically significant (p = 0.030), but this was not maintained at 3-month (p = 0.345) or 6-month (p = .086) follow-up. However, 7/9 people had lost weight at the 6-month follow up.

Results showed improvements in weight-related self-efficacy and dietary choice. One person had a depression score above clinical cut-off (measured on the PHQ-9) before starting Balance, this reduced to below clinical cut-off by the end of Balance. These results, together with the qualitative feedback about positive psychological changes suggest that third wave-informed approaches may be helpful for weight management. As clients reported that they were preparing for long-term change, this suggests that longer follow-up periods may be important in such interventions.

Weekly weighing was optional and no focus group participants discussed self-monitoring which has been shown to be effective for weight loss (NICE, 2014). Given that the focus group showed that participants valued learning about the evidence-base, clients may also welcome hearing the evidence for self-monitoring. This might also have a positive impact on weight loss outcomes as a systematic review of self-monitoring using longitudinal studies found that regular self-weighing is associated with weight loss, and not with negative psychological outcomes (Zheng et al., 2015).

All clients completed a readiness to change assessment prior to starting Balance however during the focus group, 2 out of 6 participants said that they had

not been ready to change. This suggests that clients wishing to access a service may present as ready to change in order to meet course acceptance criteria. One possible explanation is that because this was a pilot, clients may have been unsure whether the opportunity to participate would re-occur. As such, detailed consideration of motivation to change is indicated. Also, qualitative results showed an awareness of the opportunity to re-take the course if the current attempt was unsuccessful. The potential for a future attempt may be understood by a theoretical model of repeat dieting theory (Polivy & Herman, 2000). This model posits that the early, successful stages of dieting are rewarding. These rewards, together with unrealistic expectations, may override the knowledge of previous failures and allow a further change attempt. The dieter then makes external attributions to explain away failure which permits a future attempt. This model could inform weight management by highlighting the importance of having realistic goals and noticing cognitions and behaviours.

Finally, focus group participants valued the experiential exercises. Research shows that imagery manipulation exercises may support change in eating behaviours, for example, by reducing snacking (Andrade, Khalil, Dickson, May, & Kavanagh, 2016). Including these exercises in Balance may be acceptable to clients and also support behaviour change.

Recommendations

The recommendations were shared in a meeting with the service and are presented below. The service's feedback on the project is at Appendix G.

Table 3

Recommendations and service feedback

Recommendation 1: Review 'readiness for change' assessment

- Review readiness to change during the course, to assess whether participants have moved from Action back to Contemplation.
- If motivation has changed, determine whether the course can provide additional support to move the client back to the Action stage.

- Factor in the 'readiness for change' stage in the quantitative outcome measure analysis.

Rationale: To ensure group members are ready to make changes
Service response: The service will consider whether to accept clients who are not at the the 'Action' stage however would like to attend the group, and consider whether readiness to change should be monitored on a more regular basis. Also, the service are currently reviewing their readiness for change measure and are considering the self-report S-Weight (Andres, Saldana, & Gomez-Benito, 2009) and P-Weight (Andres, Saldana, & Gomez-Benito, 2011).

Recommendation 2: Add additional information about understanding the repeat dieting cycle

- Include evidence about the challenges of change, such as the 'False Hope Syndrome' to explain repeat dieting (Polivy & Herman, 2002) which might provoke discussion.

Rationale: To help group attendees develop more realistic cognitions about why previous attempts have failed – and to notice if they are moving from Action to Contemplation.
Service response: The service will consider adding this model to their information on the repeat dieting cycle.

Recommendation 3: Review course guidance on self-monitoring of weight and energy consumption

- Consider including goal setting and self-monitoring in a way that fits with the course philosophy.
- Consider whether self-monitoring should be part of the contractual obligation from the outset
- Provide information about a range of self-monitoring tools, such as apps.

Rationale: Greater alignment with NICE guidelines.

Service response: The service raised concerns about regular weight monitoring, stating that weight monitoring may lead people to take short cuts to reduce their weight in time for weigh-day, at the expense of longer-term success. The service noted that weight management courses with a behavioural focus are often successful in the short term but often weight is regained over the longer term.

The service discussed the idea of 'adding in' nutritious feed rather than focusing on removing unhealthy foods. This idea tied in with focus group theme "benefits beyond weight loss" as participants discussed a renewed interest in exploring nutritious ingredients and cooking 'from scratch'. However, this idea could be presented in terms of the energy intake/expenditure model if a person's goal is to lose weight.

Recommendation 4: Consider introducing exercises on mental imagery

- Monitor the evidence-base on mental imagery, and consider increasing the number of experiential exercises by introducing imagery techniques.

Rationale: To introduce additional experiential exercises which might support weight loss.
Service response: The service will consider including mental imagery exercises in future groups.

Recommendation 5: Adapt course content to include content on context: life stages, transitions and health conditions

- Consider adding information on weight management in the context of life stages and transitions, in order to encourage discussion and provide guidance about weight management in certain contexts.
- Consider providing information on weight management in the context of physical and mental health conditions

Rationale: Focus group participants talked about their personal circumstances, including pain and mental health problems. It may be helpful to acknowledge the

challenge posed by such circumstances during group discussions, in order that people can share their experiences and ideas.
Service response: The service noted that it is difficult to engage in weight management when experiencing pain. Masheb et al. (2015) have shown that pain severity is a predictor of sub-optimal weight loss in weight loss programmes. As such it may be helpful for the service to consider pain when assessing potential group members.

Recommendation 6: Review outcome measures

- Given that some participants noted that they were not ready to change when starting or during the course, or that they may need to complete the course before they assimilate the information and implement changes, a longer follow-up period may be indicated.
- Outcome measures that reflect the changes experienced might include weight and non-weight related changes.
- Review whether other benefits can be also be measured, e.g. quality of life, wellbeing, activity levels.
- Implement a longer-term follow up period in order to capture long-term changes in the outcome measures.
- Review how data can be collected from participants who do not attend follow-up groups.

Rationale: Participants did not think that weight measurement outcomes reflected the most important change that they experienced during the course, noting instead that a change of mind-set and a greater sense of wellbeing were more significant. However, Balance was commissioned as a weight management group.

Service response: The service acknowledged that the measures did not capture the change in wellbeing reported by the participants, but noted that they had not found any suitable measures of general wellbeing. A further recommendation was given that a study which investigated at the psychological impact of a HAES intervention (Gagnon-Girouard et al., 2010) used the validated Impact of Weight on Quality of Life (IWQOL) measure (Kolotkin & Crosby, 2002) which may capture

some of the additional changes that the participants discussed during the focus group.

Recommendation 7: Introduce a follow-up group after Balance

- Consider introducing a follow-up group that those who have completed Balance can attend.

Rationale: Weight loss was not sustained in all cases and it is possible that additional support may be beneficial after course completion. Focus group participants stated that they would welcome additional support after the course ends. Quantitative outcome measures relating to dietery choices and weight-related self-efficacy suggested that gains faded over time.

Service response: The group is not continuing in the current format due as it was not re-commissioned. The proposed new drop-in group will provide a more regular forum for people to attend.

Recommendation 8: Increase access to services

- Consider tailoring the Balance course and extending the service, for example, to children, adolescents, including people with learning disabilities.

Rationale: Focus group participants strongly suggested that access to the course material is extended more widely.

Service response: The service acknowledged the request for continued access to Balance course. The new drop-in would use much of the material from the original group. The service noted that people with learning disabilities are welcome to access the services, but as yet there has not been a specific demand for this service. Materials could be adapted if required, depending on individual need.

Project outcomes and next steps

In August 2017, a commissioning decision was made not to run the Balance again due to a lack of funding and insufficient evidence for its success based on weight-related outcomes at the end of Balance and 3-month follow-up data. Although service user feedback from the end of course questionnaires were available to the commissioners, the focus group results were not available at this time. The focus group results showed that participants found Balance extremely valuable even if weight loss had not yet been achieved as the course prepared them for change. Weight loss was the primary outcome of importance to the commissioners, but the focus group results show that this was not the most important factor for the service users. This suggests that it may be important to include the service user voice to a greater extent in weight-management commissioning decisions and service design, particularly as these results suggest that weight loss is not the only or most valued benefit that the participants gained from Balance. It is also important that services capture these less tangible benefits where possible.

Following this decision not to recommission Balance, the service decided to design a new monthly drop-in service. The launch date for this service is currently unknown due to a change of commissioning personnel. The recommendations from this improvement project are being used to inform the design of the new drop-in group. The service will: review the readiness for change assessment, consider including a mental imagery exercise; consider including additional information about the theory of repeat dieting to the current information on the dieting cycle and consider whether the current approach to self-monitoring should be adjusted in line with the current evidence-base.

Project limitations

Only one client attended all 12 Balance sessions and it is possible that missing sessions impacted effectiveness. The pilot had a small *n* and so results must be interpreted with caution. A further methodological limitation is that some of the weight change data collected at the 6-month follow-up was self-report (n=4) which is known to lead to under-reporting of weight (Connor Gorber, Tremblay, Moher, & Gorber, 2007). Finally, the focus group participants were aware that Balance was a pilot with a risk that the group would not be continued. As the group wanted the pilot to be extended, the feedback may have been positively skewed.

Future research

Further research is needed to determine the efficacy of interventions in relation to their theoretical underpinning. This is particularly important for programmes with a limited evidence-base such as those underpinned by third wave approaches. It would also be useful to conduct studies with a larger sample, particularly to enable sub-group analysis to be undertaken, for example, to determine whether the intervention is differentially effective depending on starting weight or BMI.

Conclusion

This project assessed Balance's effectiveness and offered improvement recommendations which could inform subsequent groups. Analysis using non-parametric statistics showed that at the end of Balance there was a statistically significant decrease in group mean weight but this was not maintained at 3-month or 6-month follow-up. In terms of mental health, non-parametric tests did not show a statistically significant decrease in PHQ-9 scores for depression ($p = 0.325$) nor in generalised anxiety scores measured using the GAD-7 ($p = 0.914$). Improved weight loss outcomes might be seen through aligning the course with the evidence of self-monitoring. However, as results showed that the attendees valued the course emphasis on choice, this suggests it would be important to maintain this ethos. These results provide further evidence for the efficacy and acceptability of Tier 2 group weight management programmes underpinned by 3rd wave approaches.

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Chapter 3: Main Research Project

Project Title: What are the cognitive-behavioural predictors of recovery and persistence of dizziness following assessment at an NHS vestibular clinic?

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Target journal: Cognitive and Behavioral Practice (Appendix K).

Abstract

Purpose: This study aimed to identify which cognitive and behavioural factors were associated with self-rated dizziness handicap at assessment and persistence six-months after assessment at an NHS vestibular clinic. This study used questionnaire data to explore these associations in a clinical population with mixed diagnoses of dizziness and imbalance, regardless of treatment intervention or diagnostic category.
Method: Participants (N=39) completed questionnaires shortly after assessment at an NHS vestibular clinic (Time 1) and at a 6-month follow-up (Time 2). Data were explored using bivariate and partial correlations to assess the relationship between dizziness handicap, severity and the cognitive-behavioural factors of dizziness beliefs, safety-seeking behaviours, body vigilance and health anxiety.
Results: At Time 1, safety-seeking behaviours and dizziness beliefs were associated with dizziness handicap (DHI), even when dizziness severity, anxiety, depression were controlled for. There was no relationship between health anxiety and dizziness handicap, or body vigilance and dizziness handicap. A multiple regression using T2 data was planned but not completed due to a small sample size.
Conclusions: Results suggest the importance of assessing and treating safety-seeking behaviours, beliefs about dizziness and body vigilance at clinical assessment, regardless of diagnosis or treatment offered. Clinical implications are discussed whilst remaining cautious of interpretations limited by a small sample size.

Key words

Cognitive-behavioral; dizziness; vertigo; vestibular rehabilitation.

Background and Literature Review

Dizziness describes a feeling of light-headedness, imbalance, or unsteadiness (Heinrichs, Edler, Eskens, Mielczarek, & Moschner, 2007) with vertigo involving a false perception that either the environment is moving (objective vertigo) or the person themselves is moving (subjective vertigo). Vestibular disorders can cause dizziness, vertigo and imbalance, and are grouped into three causal categories based on pathophysiologic mechanisms: structural, functional and psychiatric (Dieterich & Staab, 2017).

Structural causes can involve the inner ear or central nervous system. Peripheral vertigo (inner ear) diagnoses include labyrinthitis, vestibular neuritis/neuronitis (VN), Ménière's disease and benign paroxysmal positional vertigo (BPPV). Central nervous system diagnoses include vestibular migraine and vestibular schwannoma. Dizziness is also related to a number of psychiatric problems including panic disorder, anxiety and depression (Dieterich & Staab, 2017) although the causal relationship is not always clear. Functional causes of dizziness refer to change in organ functioning which is not attributable to either structural or psychiatric causes. Persistent postural-perceptual dizziness (PPPD) refers to chronic non-vertiginous dizziness where the patient more vaguely describes their symptoms, experiences hypersensitivity to movement, and worsening of symptoms when there is complex visual stimuli (Ruckenstein & Staab, 2009). PPPD includes conditions of chronic subjective dizziness (CSD), phobic postural vertigo (PPV), visual vertigo and space-motion discomfort (SMV) (Dieterich & Staab, 2017).

Prevalence, persistence and recovery from dizziness

A primary care survey (N=2064) found that 20% of patients experienced dizziness, persisting for >5 years for 30% of these (Yardley, Owen, Nazareth, & Luxon, 1998). Dizziness is associated with significant healthcare costs and a study of U.S. emergency departments found associated costs of $4 billion per annum, representing 4% of all ED costs (Saber Tehrani et al., 2013), a clear indication of the need to find more effective treatments.

Dizziness can resolve naturally through compensation, although intervention may include medication, surgery and vestibular rehabilitation (VR). VR is an effective physiological treatment encouraging compensation through balance system stimulation and postural control exercises using the mechanisms of

adaptation, habituation and substitution (Han, Song, & Kim, 2011). Recovery is influenced by cognitive, behavioural and emotional responses to symptoms (Yardley & Redfern, 2001). For example, dizziness is associated with avoidance of movement behaviours which slows recovery as the balance system does not receive the necessary stimulation for recalibration. VR is not always available and a survey of GP practices (N=53) found that only 13.3% of patients were referred on for specialist treatment (Jayarajan & Rajenderkumar, 2003).

Dizziness typically resolves between 6 weeks and 6 months (Luxon, 2004) However, a proportion of individuals do not recover from dizziness, despite having equivalent organic pathology. For example, in BPPV, the condition persists in approximately 30% of patients (Strupp, Dieterich, & Brandt, 2013) Patients can develop secondary somatoform vertigo and dizziness where symptoms persist despite clinical resolution (Tschan et al., 2013), and psychopathology. Research shows that psychopathology development is associated with pre-occupation with symptoms and dysfunctional cognitions in VN (N=93) (Godemann, Schabowska, Naetebusch, Heinz, & Strohle, 2006) and fear of bodily sensations and related cognitions in a mixed diagnostic sample (N=210) (Radziej et al., 2018).

This evidence suggests that psychosocial factors may be as important in dizziness persistence as biological ones.

Psychological factors associated with dizziness persistence and recovery

Psychological factors affect dizziness severity, impairment and persistence, so understanding these relationships is a key clinical issue (Ruckenstein & Staab, 2009). Godemann et al. (2005) conducted a prospective study (N=75) of vertigo persistence in VN (structural dizziness). Symptoms, emotions and cognitions were measured within 6 months of dizziness onset and at 1-year follow-up. At follow-up, 29% of the variance in symptom severity was explained by baseline anxiety-related apprehension and fear of general bodily sensations suggesting that these cognitive factors may predict dizziness persistence in VN.

Heinrichs et al. (2007) considered the relationship between a fear of bodily sensations and dizziness persistence in hospital patients (N=51) with either VN or BPPV which was expected to resolve before follow-up. Psychological and medical assessments were completed at admission (within 10 days of vertigo/dizziness onset) and at 3-months using measures including Anxiety Cognitions questionnaire

(ACQ) and Body Sensations Questionnaire (BSQ). At follow-up, a fear of bodily sensations at admission predicted dizziness persistence but ASC results did not – a result found in VN but not in BPPV, possibly explained by the initial dizziness severity being worse in BPPV and patients being less able to control it through limiting movements. As dizziness was expected to resolve for all patients, the study suggests the importance of addressing a fear of bodily sensations at assessment. Similarly, a longitudinal study (Pollak, Segal, Stryjer, & Stern, 2012) looking at beliefs and emotions in BPPV found that despite apparent clinical resolution, patients (N=37) did not show a statistically significant difference in measures of Dizziness Handicap Inventory (DHI), IPQ-R, IUS and the STAI at the 2 to 3-month follow-up point - with the exception of perceived physical handicap (DHI physical subscale). Beliefs and emotions remained in-tact in this group, again indicating the importance of working with beliefs during assessment and treatment.

A study exploring factors contributing to dizziness handicap (Yardley (1994) was conducted with a clinical sample of vertigo patients (N=101) over 7-months. Questionnaire measures included: dizziness symptoms (VSS), dizziness handicap (Vertigo Handicap Scale, VHS) and Hospital Anxiety and Depression Scale (HADS), and at Time 2 only, the Dizziness Beliefs Scale (DBS). The results showed that fear of losing control and report of autonomic symptoms were related to handicap persistence suggesting that negative beliefs about symptom controllability may contribute to long term dizziness handicap.

Yardley, Beech, and Weinman (2001) developed a longitudinal intervention study using a clinical sample (N=76) attending their GP surgery with a problem of dizziness or vertigo (excluding non-vestibular and complex/progressive central nervous system disorders). Participants were randomly assigned to either VR or a no-treatment group, and completed measures of: vertigo symptoms (VSS), handicap (Vertigo Handicap Questionnaire, VHQ) and dizziness beliefs (Dizziness Beliefs Scale, DBS) at assessment and at 6 weeks and 6 months. A 30-minute intervention consisting of education about dizziness and compensation, plus exercises and relaxation. A multiple regression analysis showed that dizziness handicap at follow-up was predicted by baseline beliefs and there was no effect of intervention. The results suggest the importance of addressing negative dizziness beliefs (Yardley et al., 2001).

Cognitive behavioural therapy (CBT) for dizziness

The role of cognitive and behavioural factors in dizziness persistence has been explored in studies using VR and CBT. An intervention study (Schmid et al., 2018) of people with either dizziness or dizziness plus imbalance (N=32) found that receiving an 8-week group treatment of VR plus CBT was effective for the dizziness-only group, but not for imbalance. The authors suggest that patients with imbalance may need more intensive psychological support and additional intervention such as physiotherapy (Schmid et al., 2018). This indicates that assessing for imbalance may be important in dizziness treatments.

The efficacy of CBT for treating phobic postural vertigo (PPV – a 'functional' dizziness) was explored in a non-randomised controlled study (Holmberg, Karlberg, Harlacher, Rivano-Fischer, & Magnusson, 2006). Patients (N=39) at a hospital-based balance disorders clinic were alternately allocated to one of two groups: self-treatment intervention (including VR) or self-treatment plus CBT. Results showed significant but small improvement in symptom severity and vertigo handicap scores in the self-treatment group and a significant additional effect in the CBT group with regards to handicap, anxiety and depression. Again, this suggests CBT is a useful addition to standard treatment (Holmberg et al., 2006).

CBT was compared to wait-list control in an RCT (N=41) with people with chronic subjective dizziness (CSD). Patients were randomly allocated to the groups and the treatment group showed significant reductions in dizziness handicap, dizziness symptom severity and avoidance and safety behaviours. (Edelman, Mahoney, & Cremer, 2012), demonstrating how CBT can reduce handicap and psychological distress in CSD. Considered together, these CBT treatment studies support the argument that targeting cognitive behavioural factors (particularly fear and avoidance) can reduce persistence of dizziness across a range of diagnostic groups.

Psychological models of dizziness

Building on the evidence cited above, and work by Staab (2012), a cognitive-behavioural model of PPPD (Whalley & Cane, 2016) suggests that dizziness persists when maintained by: unhelpful appraisals (perception of threat), safety-seeking behaviours, avoidance, and attention (e.g. selective attention to dizziness-related body sensations). This biopsychosocial model is based on cognitive

behavioural models of health anxiety (Salkovskis & Warwick, 1986), and proposes that health-related stimuli (particularly dizziness and imbalance, as well as health information, medical consultations) are misinterpreted as overly negative, leading to unhelpful behavioural reactions (avoidance, hypervigilance, attentional focus on body sensations and reassurance seeking). These counterproductive responses prevent disconfirmation leading to a vicious cycle of distress (Salkovskis & Warwick, 1986).

There is growing interest in models of health anxiety in persistent physical symptoms and it has been shown to be a common presentation in medical settings (e.g. (Tyrer et al., 2011) with evidence that treatment is clinically beneficial and cost effective (Daniels & Sheils, 2017; Tyrer. et al., 2011). Whalley and Cane (2016) have posited that this might be relevant in PPPD, and it is yet to be explored in dizziness more generally. Similarly, a general biopsychosocial CBT model for persistent physical symptoms (PPS) has been proposed which considers the interaction between life experiences, physiological factors, distress intolerance, symptoms, cognitive processes (e.g. negative cognitions and cognitive style), behaviours (e.g. avoidance, safety-seeking), and social factors (Deary, Chalder, & Sharpe, 2007). The importance of these factors has been shown in PPS including tinnitus (McKenna, Handscomb, Hoare, & Hall, 2014), 'medically unexplained symptoms' (Deary et al., 2007) and chronic fatigue syndrome (Daniels & Loades, 2016).

This evidence indicates that the cognitive and behavioural factors including avoidance, hypervigilance and health anxiety may be relevant across diagnoses in persistent dizziness, particularly given their relevance in other physical health conditions.

Study aims

Despite the evidence cited above cognitive behavioural factors are not considered or targeted as standard in vestibular services. This study aimed to explore whether the factors posited to underpin persistent dizziness in PPPD (and other PPS) also apply to dizziness across diagnoses. In particular, this study explored associations between dizziness severity and handicap, and cognitive behavioural factors of safety behaviours, beliefs, body vigilance, health anxiety, general anxiety and depression.

Measures were collected following initial assessment at an NHS vestibular clinic (Time 1), and 6 months later (Time 2). The prospective design allowed for an analysis of how the presence of cognitive behavioural factors at assessment was associated with both concurrent symptoms and persistent symptoms at follow-up. The study used a broad clinical sample in a clinical setting, unrestricted by diagnostic category. The inclusion of the Health Anxiety Inventory (Salkovskis, Rimes, Warwick, & Clark, 2002) was novel in this population. It was anticipated that the study results could inform future developments in assessment and treatment of dizziness with an aim to reduce persistence and distress.

Study hypotheses

The primary hypothesis was that dizziness handicap and dizziness severity would be correlated but that higher scores on the cognitive behavioural factors at Time 1 (beliefs about dizziness, safety-seeking behaviours, body vigilance and health anxiety) would be significantly correlated with dizziness handicap (measured using the DHI) at Time 1, even when dizziness severity, anxiety and depression were controlled for.

The secondary hypotheses were: (a) handicap and symptom severity scores would show a significant decrease from T1 to T2, (b) Scores on the cognitive-behavioural factors at Time 1 would be significantly correlated with dizziness severity (measured using the VBRQ) at Time 1, even after controlling for anxiety and depression; (c) Higher scores on the cognitive-behavioural factors at Time 1 would explain unique variance in dizziness handicap (DHI) at Time 2 after controlling for symptom severity, anxiety and depression at Time 1.

Method

Participants

Participants were identified on presentation to an NHS vestibular clinic for assessment with a clinical scientist or an advanced audiologist. Sixty-seven people expressed an interest in the study and 39 participants completed questionnaires at Time 1 (T1). Due to an unexpectedly slow recruitment rate and despite attempts to increase this, the T1 recruitment window was extended by an additional six months, with the result that T2 data collection is still ongoing. At the time of writing, 91% of those due to complete the T2 questionnaires had participated (n=19).

The sample (N=39) was predominantly female (n=25, 64.1%) with a mean age of 52.49 (SD 17.54). Symptom duration range was large (mean: 42.41, SD 85.95, range: 2 – 480 months). 41% of the sample described their ethnicity as White British but ethnicity data was not recorded for 59% of the sample. The diagnostic profile of the same was as follows: vestibular weakness (23.1%); mixed diagnoses (20.5%); BPPV (17.9%); vestibular migraine (12.8%); unclear/not recorded (7.7%); peripheral vestibular disorder (5.1%); vestibular tone imbalance (5.1%); acoustic neuroma (2.6%); labrynthitis (2.6%); vestibular neuritis (2.6%).

Inclusion criteria were sufficient English language to understand and complete the questionnaires and aged over 18 years. Participants were excluded if the clinician determined that the patient did not have rehabilitation potential, e.g. complex co-morbidities.

Table 1

Measures

Measure	Description
Primary measure – dizziness handicap: Dizziness handicap inventory (Jacobson & Newman, 1990)	A validated, 25-item self-assessment measure of the impact of dizziness. Three subscales consider physical, emotional and functional impact of symptoms. Item responses are recorded as either: “no”, “sometimes” or “always”. The total score is given from 0 (no self-perceived disability) up to a score of 100 (severe disability). The scale has good internal consistency and excellent test-retest reliability (Jacobson & Newman, 1990).
Dizziness symptoms and consequences: Vestibular Rehabilitation Benefit Questionnaire (Morris, Lutman, & Yardley, 2008, 2009)	A validated, 22-item questionnaire measuring dizziness symptoms and their consequences on a typical day over the past week. The scale has two parts: Part A – Symptom Summary and Part B – Quality of Life. The scale has excellent internal consistency (VRBQ Total α 0.89) and test-retest reliability (VRBQ total 0.92) (Morris et al., 2009).

Health anxiety: *Short Health Anxiety Inventory* (Salkovskis et al., 2002).	A validated,18-item questionnaire assessing health anxiety, including worry about health, awareness of bodily sensations or changes, and feared consequences of having an illness. Items consists of a group of four statements in which the completer selects the statement that best reflects their feelings over the past 6 months. The main scale has a satisfactory internal consistency (α 0.89) and test-retest reliability is adequate (r=.87) (Alberts, Hadjistavropoulos, Jones, & Sharpe, 2013).
Beliefs about dizziness: *Short Dizziness Beliefs Scale* (L. Yardley et al., 2001)	A validated, 11-item scale which is concerned with the negative anticipated consequences of dizziness. The scale consists of 11 statements with response options are selected from a 5-point Likert-like scale ranging from 1 (Strongly Agree) to 5 (Strongly Disagree). Internal reliability for this scale is α=0.89 and test-retest reliability is 0.63 (Yardley & Redfern, 2001).
Body vigilance: *Body Vigilance Scale* (Schmidt, Lerew, & Trakowski, 1997)	A validated, 4-item scale which is concerned with conscious attendance to internal physical cues. Completers rate how sensitive they have been to internal bodily sensations such as heart palpitations or dizziness over the past week. The scale has an eleven point Likert scale ranging from 0 (Not at all like me) to 10 (Extremely like me). The scale has good internal consistency (α=0.83) and adequate test-retest reliability (r=0.68) (Schmidt et al., 1997).
Safety-seeking behaviours: *Physical Symptoms and Behaviour* (Behaviour-P) scale (Carrick & Salkovskis, 2016).	An un-validated 18-item scale which measures CBT-related behaviours in persistent physical symptoms, selected as no validated scale was available to assess general behavioural change in persistent physical symptoms. The completer must indicate the extent to which they agree or disagree with the statements about physical symptoms by circling a number on a scale, from 1 to 10 (Carrick & Salkovskis, 2016).

Anxiety, depression:	A validated, 7-item questionnaire which measures symptoms of anxiety Completers rate the extent to which they have been bothered by symptoms over the past two weeks. Items are rated on a 0-3 scale. A total score of 8 or more indicates clinically significant anxiety symptoms. The scale has excellent internal consistency (α=0.92) and good test-retest reliability (r=0.83) (Spitzer et al., 2006).
Generalised Anxiety Disorder Scale - GAD-7 (Spitzer et al., 2006)	
Patient Health Questionnaire - PHQ-9 (Kroenke et al., 2001)	A validated, 9-item measure of depression severity. It measures depressive symptoms over the past 2 weeks. Nine items are rated on a 0 to 3 scale. A total score of 10 or more indicates clinically significant depressive symptoms. The scale has excellent internal consistency (α=0.89) and excellent test-retest reliability (r=0.84) (Kroenke et al., 2001).

Procedure

Recruitment occurred from August 2017 to May 2018, and three NHS vestibular clinics were included as Participant Identification Centres (PICs). The PICS were audiology-led clinics for patients with vestibular disorders / balance difficulties as well as issues related to hearing. These clinics were accessed by patients either through GP or via referrals from medical specialists (usually neurology and Ear Nose and Throat). The clinics offered assessment and diagnosis, and rehabilitation services were available where appropriate. Eligible participants were identified by their assessing clinician and given information about the project. Interested parties completed an Expression of Interest (EOI) form where they consented to be contacted by the researcher and were given the Participant Information Sheet, consent form and T1 questionnaires (Appendices L - O).

Participants completed the consent form and the T1 questionnaires in the two weeks following their assessment appointment, either on paper (n=34) or online (n=5). They were provided with a shorter set of questionnaires for T2 which was 6-months later (primary measures only). Following receipt of T1 questionnaires, participants were sent a £5 gift card as a token of thanks.

Ethical approval was granted by the East Midlands - Derby Research Ethics Committee, the Health Research Authority and the University of Bath Psychology Department Ethics Committee (see Appendices O, P, Q). Local research and development offices for each of the PICs approved the study.

Analysis

Data were screened for outliers, assumptions of normality, linearity, collinearity, homogeneity and independent errors using SPSS. Where assumptions were not met non-parametric statistics were used. Six out of 39 T1 responses contained missing data items. Of these, four participants had missed one item on one questionnaire, one participant omitted to complete one questionnaire in its entirety and one participant missed 16 items over two questionnaires. Missing data was imputed according to the questionnaire author's guidance. Literature was searched for guidance on handling missing data items for each scale. Where none were available, missing data was handled using median imputation. Where more than 20% of the data was missing for a questionnaire it was omitted from the analysis (n=1).

A series of bivariate correlations were planned to assess the relationship between (a) dizziness handicap (DHI) and the cognitive-behavioural variables; (b) dizziness handicap and dizziness impact.

A series of partial correlations were planned to assess the contribution of the the variables to dizziness handicap, once severity, anxiety and depression were controlled for:

(a) Dizziness handicap (controlling for anxiety and depression) and symptom severity (VRBQ total and subscales);

(b) Dizziness handicap and cognitive-behavioural variables controlling for symptom severity ((i) VRBQ-symptoms, anxiety and depression (ii) VRBQ-symptoms, (iii) Total VRBQ);

(c) Symptom severity (Total VRBQ) and cognitive-behavioural variables (controlling for anxiety and depression).

A hierarchical multiple regression analysis was planned to assess whether the cognitive behavioural factors accounted for unique variance in dizziness handicap change scores at T2 when T1 DHI was controlled for. Due to slower than anticipated recruitment, and despite repeated efforts to increase rate of recruitment

into the study, collection of T2 follow-up data is ongoing and there was only complete data for a subset of participants (n=19). As such the model was significantly underpowered and is not reported.

Results

Data were statistically analysed using Statistical Package for the Social Sciences (SPSS) version 24. Following initial analysis, two outliers were found on two scales (VRBQ and BVS) however these were mild so not excluded. Bootstrapping was used (BCa 95%, set at 1000 samples).

Table 2

Sample characteristics

	Total sample
Number of participants at T1	39
Number of participants at T2	19
Gender	Female: 25 (64.1%)
	Male: 14 (35.9%)
Age (years)	Mean: 52.49 (SD 17.54)
	Range 24-89
Ethnicity	White British: 16
	Not recorded: 23
Symptom duration at T1 (months)	Mean: 42.4 (SD 85.95)
	Range: 2 – 480
	Modal duration: 2 months

T1 Analysis - bivariate correlations

Bivariate correlations were run to explore the associations between dizziness handicap, symptom severity, quality of life and cognitive behavioural factors at Time 1 (Tables 3 and 4). The assumptions of skew were not met for the variables VRBQ quality of life (z=2.92) and VRBQ Total (z=2.72) so non-parametric tests were used with these variables.

There was a statistically significant relationship between DHI and all VRBQ variables: dizziness symptoms (VRBQ-Symptoms, r=.641, p<.001), quality of life (VRBQ-QoL, r=.643, p<.001) and VRBQ total (r=.783, p<.001).

There was a large, statistically significant, positive relationship between the DHI and behaviour (r=.792, p<.001) a large, statistically significant, negative relationship between the DHI and beliefs (r= -.615, p<.001) and a small, significant, positive relationship with body vigilance (r=.318, p=.029). This indicated that more safety-seeking behaviours, more strongly held negative beliefs and greater vigilance to body sensations were associated with greater handicap, as predicted. Contrary to the hypothesis, the relationship with health anxiety was not significant (r=.200, p=.115).

Table 3

Non-parametric tests: correlations between DHI score and key variables for whole sample at T1

Measure	Correlation Coefficient	Sig. (1-tailed)	N	BCa bootstrapped 95% CI
VRBQ Total	.783	.p<.001	38	.583 - .892
VRBQ-Symptoms	.641	p<.001	38	.400 - .804
VRBQ-QoL	.643	p<.001	38	.392 - .825

Table 4

Parametric tests: correlations between DHI score and key variables for whole sample at T1

Measure	Correlation Coefficient	Sig. (1-tailed)	N	BCa bootstrapped 95% CI
Behaviour (Behaviour-P)	.792	p<.001	38	.673 - .876
Beliefs (DBS)	-.615	p<.001	38	-.781 - -.404
Body vigilance (BVS)	.318	.029	36	.005 - .591

Health anxiety (HAI)	.200	.115	38	-0.89-.471

T1 Analysis - partial correlations

A series of partial correlations were carried out to explore the relationship between dizziness handicap and the cognitive behavioural variables (Tables 5-6). After controlling for symptom severity, anxiety, depression a statistically significant, moderate relationship remained between dizziness handicap and safety-seeking behaviours (r(32)=.556, p<.001, BCa CI=.177-.771) and dizziness handicap and beliefs r(32)=-.523, p=.001, CI=-.738 - -.252). There was no statistically significant relationship between dizziness handicap and health anxiety (r(32)=-.207, p=.121, BCa CI=-.597-.138) and the significant relationship with body vigilance disappeared (r(31)=-.212, p=.118, BCa CI=-.537 - .102). As an exploration, similar analyses were run whilst controlling for VRBQ-Symptoms only, and VRBQ-Total and the same factors showed statistical significance.

Table 5

Partial correlations using bootstrapping method: Dizziness handicap and cognitive behavioural variables (controlling for symptom severity, anxiety and depression)

Measure (Control)	Behaviour-P	DBS	BVS	HAI
Dizziness handicap (symptom severity, anxiety, depression)	r(32)= .556 p<.001 (BCa CI=.177-.771)	r(32)= -.523 p=.001 (BCa CI= -.738 - -.252)	r(31)= -.212 p=.118 (BCa CI= -.537 - .102)	r(32)= -.207 p=.121 (BCa CI= -.597-.138)
Dizziness handicap (VRBQ-symptom severity)	r(35)=.688 p<.001 (BCa CI .433-.833)	r(35)= -.567 p<.001	r(33)=-.016 p=.464	r(35)=-.044 p=.397

		(BCa CI-.730 – -.374)	(BCa CI=-.361 - -.275)	(BCa CI=-.425 - .309)
Dizziness handicap (VRBQ).	r(35)=.548 p<.001 (BCa CI=.262 - .738)	r(35)= -.325 p=.025 (BCa CI-.583 – -.073)	r(33)=-.069 p=.347 (BCa CI-.377-.234)	r(35)= -.206 p=.110 (BCa CI=-480 - .104)

Table 6

Partial correlations using bootstrapping method: Total VRBQ and cognitive behavioural variables (controlling for anxiety and depression)

Measure (Control)	Behaviour-P	DBS	BVS	HAI
Total VRBQ (anxiety, depression)	r(33)=.491 p=.001 CI=-.107 - .747	r(33)= -.487 p=.002 CI= -.745 - -.126	r(32)=.183 p=.150 CI=-.060 - .446	r(33)= .218 p=.104 CI=-.147 - .534

Time 1 and Time 2 comparison – related samples comparison and regression analysis

T1 and T2 (n=19) data were compared on the total DHI score. The mean DHI score reduced from 41.6 (SD 21.5) at T1 to 32.9 (SD 28.6) at T2 but a Wilcoxon signed-rank test showed that the difference was not statistically significant (t= 58.0, z= -1.199, p=.115, r= 0.194, one tailed). Comparison of the scores on the DHI showed that 8 (42.1%) participants had increased handicap, 10 (52.6%) had decreased handicap and 1 (5.3%) participant saw no change (Table 7).

T1 and T2 (n=19) data were compared on the total VRBQ score. The mean

VRBQ score reduced from 39.7 (SD 21.1) at T1 to 25.9 (SD 25.4) at T2 but a Wilcoxon signed-rank test showed that the difference was not statistically significant (t= 43.5, p=.67, z= -1.829, r=0.305, one-tailed). The median VRBQ score at T1 was 37.0 and at T2 was 20.5.

A series of bivariate correlations (Pearson's) examined the relationship between T1 cognitive behavioural factors and T2 DHI. There was a statistically significant relationship between T2 DHI and T1 behaviour (r=.392, p=.048, one tailed) but the relationship with the other cognitive behavioural variables (health anxiety, body vigilance and dizziness beliefs) were not statistically significant (p>.05).

A series of bivariate correlations (Pearson's) examined the relationship between T1 cognitive behavioural factors and T2 DHI whilst controlling for concurrent symptom severity and quality of life (VRBQ Total). There was a statistically significant negative relationship between T2 DHI and T1 body vigilance (r=-.505, p=.019, one tailed) but the relationship with the other cognitive behavioural variables (health anxiety, behaviours and dizziness beliefs) were not statistically significant (p>.05).

Discussion

As predicted, higher scores on safety-seeking behaviours and dizziness beliefs were significantly associated with concurrent levels of dizziness handicap, over and above levels of dizziness symptom severity, anxiety and depression. This suggests that behaviours and beliefs may be particularly important factors relating to dizziness handicap, in line with previous research indicating that treatment (CBT) designed to reduce avoidance and safety-seeking behaviours, as well as hypervigilance and attention is effective for reducing dizziness handicap (Edelman et al., 2012). Of particular interest is the finding that these significant associations were moderately large (r=.792 and r=-.615) even when anxiety, depression and symptom severity were partialled out.

Contrary to hypothesis, there were no such associations with dizziness handicap and body vigilance or health anxiety. This could indicate that these factors are not related to dizziness handicap, or because if health anxiety and body vigilance are experienced, they are dizziness-specific which is not captured by the

measures used. The CBT model of PPPD (Whalley & Cane, 2016) hypothesises that patients with PPPD would score more highly on the HAI than other vestibular patients, and it may be that different results would be found in diagnostic sub-groups. These results indicate that those with persistent dizziness handicap do not fit with a typical health anxiety model, but other aspects of the transdiagnostic biopsychosocial model of PPS do appear to be relevant.

Findings relating to cognitive-behavioural factors at Time 1 and concurrent symptom severity and quality of life (VBRQ Total) (independent from anxiety and depression) were partly supported. The hypothesis was upheld for behaviours (p=.001) and beliefs (p=.002), but not supported for health anxiety (p=.104) or body vigilance (p=.150). These results also suggest the importance of these two factors in relation to a total measure of dizziness severity and quality of life. This is unsurprising given the strong relationship between the measures of handicap and severity/quality of life.

In terms of the change in handicap score from T1 to T2, group means decreased on both measures but these reductions were not significant. This was unexpected as research shows that the majority of dizzy patients recover between 6 weeks and 6-months (Luxon, 2004) however in the sample, 42.1% participants reported worse dizziness handicap after 6 months (Table 7). Participant data showed that baseline symptoms had already persisted for >6 months in 51% of sample, and this problem history may explain the lower than expected proportion of the sample showing symptom resolution over 6 months. Although this limits the conclusions that can be drawn regarding the importance of cognitive-behavioural factors in first episode dizziness, this results are still relevant for understanding dizziness persistence more generally. From a theoretical perspective, the persistence of dizziness in relationship to cognitive-behavioural factors might be expected to be important regardless of symptom duration, and these factors could be particularly relevant for those with long-standing problems.

Future studies might amend the inclusion criteria relating to symptom history, in order to include only those with a first episode of dizziness whose symptoms might be expected to resolve within 6 months**.** Alternatively, studies which use a larger sample with a mixed problem history could conduct additional analysis by splitting the sample between those with first episode and longer-term symptoms, to analyse whether the cognitive-behavioural factors predict recovery.

Although change in DHI to T2 was minimal, there was a significant association between T1 behaviours and T2 handicap (p=.048). This suggests that even within a mixed diagnostic sample, safety-seeking behaviours may be important enough to predict persistence of dizziness handicap. This fits with evidence that those who avoid movement are less likely to recover, as in VR movement is important for compensation and recovery (Kundakci, Sultana, Taylor, & Alshehri, 2018) which is also evidence in that CBT with graded exposure for avoided movements increases the effectiveness of VR (Johansson, Akerlund, Larsen, & Andersson, 2001). The use of a general rather than specific measure of safety-seeking and avoidance behaviours extends these findings. The finding that beliefs was not significant was surprising given that previous research has indicated the importance of beliefs in handicap over the longer term such as Yardley and Redfern (2001) however the non-significant results may be due to lack of power.

The relationship between T2 handicap and the cognitive behavioural variables was also compared whilst controlling for T1 VBRQ Total. However, only body vigilance was statistically significant (p=.019). This indicates that this factor maybe particularly important in explaining dizziness handicap persistence, despite initial severity. However due to the small sample it will be important to repeat this analysis when full T2 data is collected.

Strengths and Limitations

This study has particular strengths including a prospective design with 6-month follow-up, it includes participants with diagnoses of mixed aetiology, who were recruited in the real-world setting of NHS clinics. It also uses measures of health anxiety and non-specific behaviours, neither of which have been used with this population.

The main limitation of this study is that fewer participants were recruited than planned, despite great efforts to increase rates and numbers recruited into the study, as such there was insufficient power for the prospective part of the design. Since the study was a non-experimental study design therefore conclusions cannot be made about causation. Selection bias may have influenced which participants were informed about the study and participation bias may have been introduced as some patients declined due to being unwell.

Validated measures were used with the exception of the Behaviour-P

questionnaire which is an un-validated scale, although it has previously been used in cognitive-behavioural research. For feasibility, severity and recovery was measured by self-report rather than clinician-reports or standardised tests, which may have reduced the objectivity. However, the chosen measure was a valid, standardised clinical measure.

It is acknowledged that there are limitations of using questionnaires to measure symptoms and recovery. Human experiences may not be easily comparable or fully captured by questionnaire answers. There may also be overlap in questionnaires, for example, the questionnaires measuring handicap and severity may measure overlapping concepts. However, such challenges are not unique to this study and were managed prior to starting recruitment, for example, by piloting the questionnaire pack with a service user, consulting the research literature and clinicians. During the project, informal feedback offered by some participants was that they found that the dizziness-related questionnaires matched with their experiences.

Clinical implications and future research

Future research could continue the development of valid and reliable measures for this clinical population, and also to validate the Behavoiur-P scale used in this study.

The study results add to growing evidence that vestibular assessment can be enhanced by including psychological aspects to assessment, particularly in identifying behaviours and beliefs that could impact on handicap and symptom severity concurrently and over time. Improving assessment, information-provision and treatment of patients with dizziness, regardless of aetiology, may involve developing a more comprehensive, biopsychosocial approach. The results do not indicate that health anxiety is a particular issue affecting dizziness, unlike evidence for this in other medical settings and PPS (Tyrer. et al., 2011).

Future research could build on these findings by gathering information from a larger sample, to also allow for additional analysis on sub-groups (e.g. diagnosis, symptom duration) and demographic variables. It would also be useful to incorporate clinical physiological measures of dizziness and imbalance at both time points to inform the results and to explore the relationship with objective measures of vestibular factors, as has recently been explored in a study of psychological

factors in VN (Cousins et al., 2017).

Conclusions

In a clinical sample of people with dizziness and imbalance of mixed aetiology, safety-seeking behaviours, dizziness beliefs and body vigilance were associated with higher dizziness handicap (even after controlling for symptom severity). The correlational nature of this finding does not allow for causal implications to be understood. Due to slow than expected recruitment, it has not yet been possible to ascertain whether the presence of such cognitive-behavioural factors at assessment are able to predict the persistence of dizziness handicap at 6-month follow-up, however data collection is ongoing and further analysis will be conducted when the full data set is available.

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Chapter 4: Executive Summary

Main research project: *What are the cognitive-behavioural predictors of recovery and persistence of dizziness following assessment at an NHS vestibular clinic?*

Background: Dizziness describes a feeling of light-headedness, imbalance, or unsteadiness and vertigo is a false perception that either environment or the person themselves is moving. Dizziness is a common problem and one which usually resolves naturally, or through treatments such as vestibular rehabilitation, medication or surgery. However, a proportion of patients do not recover, for reasons which are not explained by their symptoms or diagnoses. Research has indicated that psychological factors may be important in understanding recovery and persistence, and cognitive and behavioural factors which have been shown to be important in dizziness, and in other persistent physical health problems.

Aims: This study explored whether cognitive-behavioural factors apply to dizziness across diagnoses, as has been proposed in a model of persistent postural-perceptual dizziness (PPPD). In particular, this study explored associations between dizziness severity and handicap, and cognitive behavioural factors of safety behaviours, beliefs, body vigilance, health anxiety, general anxiety and depression. It was anticipated that the study results could inform future developments in assessment and treatment of dizziness with an aim to reduce persistence and distress.

Methods: Questionnaire data were collected at two time points: following initial assessment at an NHS vestibular clinic (Time 1), and 6 months later (Time 2). The prospective design allowed for an analysis of how the presence of cognitive behavioural factors at assessment was associated with both concurrent symptoms and persistent symptoms at follow-up. The study used a broad clinical sample in a clinical setting, unrestricted by diagnostic category. The inclusion of the Health Anxiety Inventory was novel in this population.

Hypotheses: The primary hypothesis was that dizziness handicap and dizziness severity would be correlated but that higher scores on the cognitive behavioural factors at Time 1 (beliefs about dizziness, safety-seeking behaviours, body vigilance and health anxiety) would be significantly correlated with dizziness handicap at

Time 1, even when dizziness severity, anxiety and depression were controlled for. The secondary hypotheses were: (a) handicap and symptom severity scores would show a significant decrease from T1 to T2, (b) Scores on the cognitive-behavioural factors at Time 1 would be significantly correlated with dizziness severity at Time 1, even after controlling for anxiety and depression; (c) higher scores on the cognitive-behavioural factors at Time 1 would explain unique variance in dizziness handicap (DHI) at Time 2 after controlling for symptom severity, anxiety and depression at Time 1.

Results: At Time 1, safety-seeking behaviours and dizziness beliefs were associated with dizziness handicap (DHI), even when dizziness severity, anxiety, depression were controlled for. There was no relationship between health anxiety and dizziness handicap, or body vigilance and dizziness handicap. Due to recruitment difficulties the hierarchical multiple regression model was underpowered so is not reported, and T2 data collection is ongoing.

Conclusions: In a clinical sample of people with dizziness and imbalance of mixed aetiology, safety-seeking behaviours, dizziness beliefs and body vigilance were associated with higher dizziness handicap (even after controlling for symptom severity). The correlational nature of this finding does not allow for causal implications to be understood. Due to slow recruitment it has not yet been possible to ascertain whether the presence of such cognitive-behavioural factors at assessment are able to predict the persistence of dizziness handicap at 6-month follow-up.

Chapter 5: Connecting Narrative

The aim of this section is to share my reflections on what I have learned from my research projects and case studies.

The project titles were:

- **SIP**: Service improvement project of a pilot Tier 2 weight management course, 'Balance'.
- **Literature review**: The evidence for hospital based psychological interventions in the emergency department: a systematic review
- **Main research project:** What are the cognitive-behavioural predictors of recovery and persistence of dizziness following assessment at an NHS vestibular clinic?

My case study titles were:

- **Working age adults**: Mental contamination in obsessive-compulsive disorder: a case study
- **Older adults:** Adapted Cognitive Behavioural Therapy for Depression and Anxiety with a Greek-Cypriot Older Adult
- **Learning disabilities**: Using a systemic consultation approach with a residential staff team to develop a positive behavioural support plan for an older adult with Down's Syndrome.
- **CAMHS**: CBT for misophonia in an adolescent: a single case experimental design
- **Elective:** CBT for severe fear and disgust-related needle phobia: single case experimental design.

Case Studies

Working age adults placement

This case study was about using CBT with a gentleman who had long-standing and severe OCD. This was my first experience of working with OCD and I was pleased to be co-working with a qualified clinician, who was a graduate of the Bath clinical psychology doctorate. This was also the first time I had written a clinical case report. A key learning point was the importance of identifying and setting out the heuristic value for each case report, a skill which I then used throughout training. The case study passed, but it did not meet the SCED requirements so I re-wrote it as a standard case study. Re-writing this to fully meet all of the course criteria was a challenging task, but it was an important step in understanding how to write a case study of a publishable standard. I submitted a poster based on this case to the BABCP Conference 2016.

Older adults placement

My second case study described using CBT with an older gentleman who experienced severe and enduring depression. This was a challenging case, as the client had a very fixed belief that there was a purely biological explanation for his problem and he was certain that the psychiatrist would soon find the correct curative medication. He was reluctant to try out the ideas we discussed, including the suggestions for behavioural activation. During this work I also noticed that I found the longitudinal aspects of the formulation to be valuable, particularly around the development of beliefs in early years. Although the intervention did not appear to be helpful, I developed a good therapeutic rapport with the client and his wife and I enjoyed the work.

Learning disability placement

My learning disability case study described using a systemic approaches with a staff team who supported an older adult who has Down's syndrome. I enjoyed this work as I developed my understanding of systemic theory and practice and I found it useful to use the the reflecting team technique within staff consultation meetings. My supervisors encouraged me to take the 'non-expert' position, a stance which I found quite freeing. However, I also reflected that as a clinical psychologist I

could hold expertise in systemic ideas, which could help to facilitate these discussions. In this sense, non-expert refers to expertise in the client's life, but it does not exclude a practitioner from providing expertise in psychological thinking.

I had planned to write this case as a systemic SCED to meet course requirements. Although I had a stable baseline with a systemic outcome measures at three time points, I did not take sufficiently regular measures during the intervention phase to make this eligible to meet SCED requirements. I was disappointed about this oversight, but I was also one step closer to understanding how to design and deliver SCEDs. Due to the intense workload of the doctorate, I was pleased that by writing a doctorate level systemic case study I had met two course requirements with one submission.

CAMHS placement

This case study described using CBT with an adolescent who experienced misophonia, an under-researched area with a limited evidence-base. CBT did not prove to be helpful for this client. This case was challenging from a relational point of view as it was difficult to establish a warm rapport with the client. During this placement, I shared an office with a child psychotherapy trainee who shared some of her ideas about transference and counter-transference, and these ideas provided an alternative perspective on the therapeutic relationship. I resolved to increase my familiarity with the literature around relational aspects of therapy after training. I reflected that I would like to learn more about inter-personal processes, as this area has not been extensively covered within the teaching programme. I submitted a proposal for a poster based on this case study to the BABCP Conference 2018, which was accepted with a request to present it as an open paper.

A significant achievement in terms of my training journey was that I successfully wrote this case as a SCED. I later used my experience to initiate a survey of my colleagues to find out about other trainee's experiences of completing SCEDs, the results of which were shared at the Group of Trainers Conference in 2017.

Elective placement 1: Assertive Contact and Engagement

My elective placement was with St Mungo's Assertive Contact and Engagement Team, who also ran a Step 3 IAPT service. This was my 5th and final training case study, and it was a SCED which described using CBT with a client

who had a severe needle phobia following a distressing blood test experience as a child. Whilst planning the SCED, I became aware of the potential for course requirements to conflict with what is clinically needed, for example, by using repeated outcome measures or planning an extended assessment to establish a baseline. I concluded that it is important to be open and honest about these plans with clients in order to gain informed consent.

One challenge with this case was accessing suitable measures at the start of therapy, as I was unfamiliar with the area. However, persistence paid off and I found some useful measures and also developed some idiosyncratic measures. I reflected that I find it useful to use outcome measures in my clinical work as they provide a focus for discussing progress with the client. This client was particularly motivated to make progress and I enjoyed the experience of delivering a successful treatment.

By this point in training, I noticed that my confidence had increased in a number of areas, including: planning and executing SCEDs, selecting and using outcome measures, and exploring what was going well or less well in therapy sessions. I was also more confident with collaboratively developing formulations and ensuring that the intervention linked directly with the formulation and was theoretically grounded. In the case study marker's feedback, I was asked to provide an alternative formulation for this case which I developed using a systemic approach. I had not included an alternative systemic formulation since preparing the first case study and I found this to be a useful exercise. It helped me to look at the case differently and I reflected that this was likely to be a useful approach to take to clinical work.

Service Improvement (SIP)

Prior to working in psychology, my previous career was in service design and improvement. As such, I started my planning my SIP with preconceived ideas about what a service improvement project entails. My initial project proposal passed, but I was advised to strengthen the theoretical underpinnings. I found it hard to re-work this idea and I decided that the idea fitted better as a service-facing consultancy project. I learned that the SIP in the academic context meant the application of formal research methods, something that is not always required in a 'real world' setting.

Some months previous, I had met with regional clinical psychologist Dr. Alex Stephens at the Bath DClinPsy research fair. Around the time that I was re-working my original SIP, Alex contacted with an idea for a service improvement project to evaluate and improve a weight management course called 'Balance'. This was fortuitous timing. I wrote a new proposal and I developed my original SIP idea into a consultancy project.

I used both quantitative and qualitative methods for this project. Both methods were useful but the focus group data highlighted just how important and valuable the clients found the group, with one client saying "It changed my life". This being the case, I was very disappointed to hear that Balance was not re-commissioned. However, the recommendations from the SIP were used to inform the design of the group that followed Balance and it was heartening to see the work being used.

At the feedback session, one of my recommendations was to include formal self-monitoring of energy intake and expenditure. This was discussed with the service, who expressed a view that clients do not always respond well to self-monitoring and it can be detrimental in the long-run. The service talked about an alternative weight management approach called *Healthy At Every Size* (HAES) also did not encourage self-monitoring. Weight loss is not the primary goal in HAES approach states that the body will achieve its natural weight if food if hunger and satiety cues are responded to (Humphrey, Clifford, & Neyman Morris, 2015). However, there is a lack of evidence supporting HAES at present (Penney & Kirk, 2015) metabolically healthy obesity is disputed, and evidence suggests that being overweight leads to poorer health outcomes in the longer term (J. A. Bell et al., 2015). This discussion lead me to reflect on how qualified clinical psychologists need to balance clinical judgement, the evidence-base and clinical guidelines and I reflected that it will be interesting to see how my views develop with experience.

Shortly before submitting my SIP, I attended a British Psychological Society webinar on 3rd wave interventions for obesity where I learned of some promising results relating to an intervention-based research project which sounded similar to Balance. I contacted the researcher to request in-press copy of her research paper and although I did not receive this in time, I will incorporate the findings into the write-up should I submit the paper for publication.

Systematic Literature Review (LR)

The process of defining the review topic was challenging and it took a long time to pin down a research question. Although many topics interested me, I found it hard to identify a research gap suitable for a systematic literature review. I reflected that this might have been due to being at an early stage in my career and not being deeply familiar with the research literature in any particular area.

I was interested in completing my literature review in the area of clinical health psychology and after a long search which did not generate a suitable research question, I asked my supervisor Dr. Jo Daniels whether she could point me towards potential areas for reviews. One of Jo's suggestions was to look at frequent attenders in emergency departments (ED). This idea immediately appealed to me as I am interested in the setting, I feel compassion for people who repeatedly attend the ED due to unmet needs, and because it relates to my interest in service design and improvement. It also linked with my main research project which is about persistent physical symptoms, as patients may attend the ED with these presentations.

However, when I started looking at the research literature, I noticed that many of the clinical research papers set in the ED did not report the impact on ED attendance. As such, I proposed a review which focused on psychological interventions in the ED. My initial idea was to look at interventions that started and ended in the ED, but my supervisor suspected that there would not be many papers to include and we broadened the search to include interventions started in the ED and completed within the hospital setting. This proved to be a fruitful search and the final review include 23 papers. I also pulled out the data (where included) on repeat attendance in the ED and I included a narrative summary of findings. Once I had completed my proposal and understood what was required, I enjoyed completing the review and I am pleased that I have developed this skill. A meta-analysis was not indicated in this review because of the heterogeneity of included studies, but I would like to learn how to do this in future.

The results indicated that psychological intervention is relevant and useful in emergency settings. During this process I read some articles about the innovative engagement of psychologists in paramedic services, psychiatric liaison and the emergency department which led me to think more broadly about the role of a psychologist. I concluded that there is scope for greater incorporation of

psychological assessment, formulation and intervention in emergency settings, for both physical and mental health presentations.

Main research project (MRP)

My main research project was about whether cognitive-behavioural factors predict the persistence of dizziness.

Ethical approval

I experienced the process for gaining ethical approval to be overly bureaucratic and time-consuming, and the repetition within and between the IRAS form and protocol was frustrating. However, completing these detailed documents was beneficial, as the project received NHS ethical approval following a proportionate review, with the reviewers requesting just one minor amendment. I gained useful experience by applying for ethical approval from Bath University Ethics Committee, two local NHS Research and Development Committees and the NHS Research Ethics Committee. This experience will be beneficial for conducting clinical research in the future.

Project set-up

In terms of project set-up, I also reflected that it is important to check and re-check project documents before they are issued. I did not attach one questionnaire to my original research packs, but as I spotted this omission soon after the project started I was able to rectify it. In future I would also ask a second person to help with checking, as it becomes harder to spot errors in familiar documents especially when you are managing multiple projects and working clinically.

Recruitment

Two NHS audiology clinics acted as Participant Information Centres (PICs) for my project, by giving Expression of Interest (EOI) forms to potential participants. Overall, recruitment was far slower that predicted. When I was designing the project, one PIC anticipated that they would identify 15 participants per week, whereas the reality was 0-2. Both PICs were asked for statistics on recruitment number and one replied who noted that during the time frame, about 200 assessment appointments were held, and 30 EOIs were given out. The gap was explained by clinicians forgetting to speak to patients about the study, patients declining due to poor health or being too busy, and patients being excluded due to

having complex co-morbidities.

I responded to the slow recruitment by extending the recruitment period twice, sending reminder emails to the PICS and applying for an ethical approval amendment to permit the using posters in the waiting room. My supervisor, Dr. Liz Marks worked at one of these clinics and Liz also supported me by reminding clinicians about the project.

I reflected that if the researcher is not located within or near the PIC, then influencing recruitment levels is more challenging. I learned that it is important for recruiting clinicians to be motivated to help with this task and when designing a project it is important to fully check feasibility before proceeding. I was reliant on busy clinicians who work in two different services to me, which made it more difficult to influence recruitment. In future projects, I would spend more time establishing working relationships before recruiting via a PIC, and would also think about contingency plans in case a key contact left the service as happened with one of my PICS.

The process of using an EOI form added delays which in hindsight hampered recruitment. Instead, it would have been quicker if clinicians had emailed the phone number of potential participants, and I contacted them by phone. There was a delay between the participant attending the appointment, receiving the EOI at the University (as I was only there twice a week) and calling them. By this time, the patient may have lost motivation to participate and/or lost the questionnaire pack. Also, the design of the EOI form itself created delays. The form was over complicated and asked questions about whether the patient wanted to be contacted by the researcher. If the patient selected ‘no’ then this was respected, but it is likely that a phone call to discuss the project might have been helpful for recruitment. Also, in some cases this part of the sheet was not completed making it unclear whether the patient wanted me to contact them or whether the clinician had omitted to complete the form.

During this project, I learned the importance of communicating regularly with PICs; after the initial meetings with the PICs I did not want to overwhelm the clinicians with communication about the project, but I later received feedback from one PIC requesting additional reminders, so I changed my approach. I similarly learned to be more persistent and proactive when recruiting participants; people will tell you if they want to terminate the call or not to participate. This is reflected in very

low attrition between T1 and T2.

Project Outcomes

Initial results have shown some correlations which support some of the study hypotheses. As I am still collecting data for T2 final conclusions cannot be drawn. I aim to write up the study for publication once data collection is complete which will be in Autumn 2018.

Summary

The research projects have been the most challenging aspect of the course particularly scoping the question and working out the steps required for each project. It was also difficult to complete the research projects alongside attending university, placement and with family commitments. However, now that I have completed these projects and case studies, I am pleased that I have developed these skills and I intend to use and develop them once qualified.

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My friends and family for understanding my many absences from social events.
My brother, for being there when I was not.
My mum, for your love, support and encouragement.
My partner and favourite author, James Ellis, who said that everything will be ok, and it is.

Dedication

Dedicated to the memory of my father
Paul McGuire
4th August 1949 – 24th May 2017

Appendices

Appendix A - Critical Literature Review: Target Journal Guidance for Authors

International journal of Clinical and Health Psychology.

GUIDE FOR AUTHORS

International Journal of Clinical and Health Psychology publishes manuscripts with a basic and applied emphasis, involving both theoretical and experimental areas contributing to the advancement of Clinical and Health Psychology. The Journal publishes Original Articles (empirical studies), Review Articles, Brief Reports and Case Reports. On exception the Journal publishes articles on science evaluation. The manuscripts with samples of university students whose use is not clearly justified in the objectives of the study will not be considered.

The manuscripts submitted to ***International Journal of Clinical and Health Psychology*** should not have been previously published, and should not be under consideration for publication elsewhere. All signing authors must agree on the submitted version of the manuscript. By submitting their manuscript the authors agree to relinquish their copyrights to the Journal for the duration of the editorial process. Copyrights will be transferred permanently to ***International Journal of Clinical and Health Psychology*** if the manuscript is accepted for publication.

BEFORE YOU BEGIN

Ethics in publishing

Please see our information pages on Ethics in publishing and Ethical guidelines for journal publication.

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Declaration of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests in two places: 1. A summary declaration of interest statement in the title page file (if double-blind) or the manuscript file (if single-blind). If there are no interests to declare then please state this: 'Declarations of interest: none'. This summary statement will be ultimately published if the article is accepted. 2. Detailed disclosures as part of a separate Declaration of Interest form, which forms part of the journal's official records. It is important for potential interests to be declared in both places and that the information matches. More information.

Submission declaration and verification

Submission of an article implies that the work described has not been published previously (except in the form of an abstract, a published lecture or academic thesis, see 'Multiple, redundant or concurrent publication' for more information), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder. To verify originality, your article may be checked by the originality detection service Crossref Similarity Check.

Changes to authorship

Authors are expected to consider carefully the list and order of authors **before** submitting their manuscript and provide the definitive list of authors at the time of the original submission. Any addition, deletion or rearrangement of author names in the authorship list should be made only **before** the manuscript has been accepted and only if approved by the journal Editor. To request such a change, the Editor must receive the following from the **corresponding author**: (a) the reason for the change in author list and (b) written confirmation (e-mail, letter) from all authors that they agree with the addition, removal or rearrangement. In the case of addition or removal of authors, this includes confirmation from the author being added or removed.

Appendix B - Critical Literature Review: Evidence Tables

Study characteristics						
Clinical Presentation: Panic and/or Non-cardiac chest pain						
Study ID	**Author & Year**	**Title**	**Design**	**Sample**	**Characteristics of participants Gender & Mean Age (SD)**	**Key measures**
Randomised Controlled Trials						
12	van Beek et al, (2013) The Netherlands	A brief cognitive-behavioural intervention for treating depression and panic disorder in patients with non-cardiac chest pain: a 24-week randomized controlled trial	RCT	113 participants Two groups: Intervention CBT group (n=60) Treatment as usual group (n=53)	Gender CBT: Female: 34 (56.7); Male: 26 (43.3) TAU: Female 15 (28.3); Male 38 (71.7) Age CBT: 48.7 (13.0) TAU: 49.9 (11.0)	Assessor-rated clinical global impression severity scale (CGI-severity) Hamilton depression rating scale (HDRS) Hospital anxiety and depression scale (HADS); (HADS-A) and depression (HADS-D) State-trait anxiety inventory (STAI) Fear questionnaire (FQ)
Clinical studies (Non-RCT)						
13	Dyckman et. al (1999) USA	Effects of psychological intervention on panic attack patients in the emergency department	Quasi-experimental study	354 participants. Three groups: Intervention brochure group (n=53) Intervention contact group (n=32) Control group (n= 269)	Gender Control Female 185 Male 84 Brochure Female 35 Male 18 Contact Female 28 Male 4 Age Control 49.3 (15.9) Brochure 37.9 (12.2) Contact 44.3 (15.3)	ED visit rate, 2) psychiatry department visit rate, and 3) rate of visits to all nonpsychiatric medical departments (including ED).
14	Nuthall (2007) UK	CBT-based early intervention to prevent panic disorder: A pilot study	Quasi-experimental study	27 participants Two groups: Intervention group: (n=12) Control group (n=9)	Gender Intervention: Female: 3 Male: 9 Control: Female: 4 Male: 5 Age Intervention: 38.6 Control: 35.9	Panic Disorder Severity Scale - Self-Report (PDSS-SR)
15	Swinson (1992) Canada	Brief treatment of emergency room patients with panic attacks	Quasi-experimental study	33 participants Two groups: Exposure instruction group (n=17) Reassurance group (n=16)	Gender Female 13 Men 20 Age: 31.5	Fear Questionnaire (FQ) agrophobia subscale Mobility Inventory (MI) Beck Depression Inventory (BDI) No.of panic attacks (self-assessment)
Case studies						
16	Hegel et. al (1989) USA	Behavioral treatment of angina-like chest pain in patients with hyperventilation syndrome	Case study(A/B design)	3	Gender Female: 3 Age 46, 48, 55	Behavioural observations of breathing Symptom self-report

Studies excluded on age (but included here for completeness & discussion)						
17	Esler (2001) USA	A brief cognitive-behavioral intervention for patients with non-cardiac chest pain	Quasi-experimental study	59 participants Two groups: Brief CBT intervention group (n=29) Treatment as usual group (n=30)	Gender: Female 45.5%; Male 54.2% Age: *Sample range 19 - 70* 40.73 (SD 12.04)	Chest pain frequency and severity (Chest pain interview) Anxiety Sensitivity Index (ASI) Brief Symptom Inventory (BSI) Cardiac Anxiety Questionnaire (CAQ);
18	Tyrer et al. (2017) UK	Clinical and cost-effectiveness of adapted cognitive behaviour therapy for non-cardiac chest pain: a multicentre, randomised controlled trial	RCT	68 participants Two groups: CBT-HA group: 34 Standard care group: 34	Gender CBT-HA group: Female 11 (32.35%): Male 23 (67.65%) Standard care: Female 10 (29.41%); Male 24 (70.59%) Age *Inclusion criteria: 18-75* CBT-HA group: 48.91 (14.50) Standard care: 48.71 (13.46)	Health Anxiety Inventory (HAI) Hospital Anxiety and Depression Scale (HADS) No. of attendances at A&E Health service costs
19	Lessard et al. (2012) Canada	Comparing two brief psychological interventions to usual care in panic disorder patients presenting to the emergency department with chest pain	Quasi-experimental study	58 participants Three groups: Intervention group 1-session PMI (n=24) Intervention group: 7-session CBT (n=19) Control usual care (n=15)	Gender 1-session PMI: Female 11 (46%); Male 13 (54%) 7-session CBT: Female 10 (53%); Male 9 (47%) Control: Female 6 (40%); Male 9 (60%) Age 1-session PMI: 41.08 (SD: 13.89) 7-session CBT: 46.58 (SD 13.65) Control: 39.27 (SD11.80)	PD Severity score on Anxiety Disorder Interview Schedule for DSM-IV (ADIS-IV) Body Sensations Questionnaire (BSQ) Agoraphobic Cognitions Questionnaire (ACQ) Panic and Agoraphobia Scale Anxiety Sensitivity Index (ASI) Cardiac Anxiety Questionnaire (CAQ)
20	Pelland et al. (2011)	Efficacy of 2 interventions for panic disorder in patients presenting to the ED with chest pain	Quasi-experimental cohort study	47 participants. Three groups: Intervention group drug treatment (n=13) Intervention group: Brief CBT (n=19) Control usual care (n=15)	Gender Drug intervention: Female (46%); Male (54%) Brief CBT: Female (47%); Male (53%) Control: Female (40%); Male (60%) Age Drug intervention: 40 (SD13) Brief CBT: 47 (SD 14) Control: 39 (SD 12)	PS Severity score on Anxiety Disorder Interview Schedule for DSM-IV (ADIS-IV) Agoraphobic Cognitions Questionnaire (ACQ) Anxiety Sensitivity Index (ASI) Panic and Agoraphobia Scale (PAS) Beck Depression Inventory II (BDI) Cardiac Anxiety Questionnaire (CAQ)
21	Marchand et al. (2012) Canada *(follow-up study of Lessard (2012) and Pelland (2011))*	Treatment of panic in chest pain patients from emergency departments: Efficacy of different interventions focusing on panic management	Quasi-experimental study	71 participants Four groups: Pharmacotherapy group (n=13) CBT group (n=19) One-session panic management group (n=24) Supportive care as usual (n=15)	Gender Pharmacotherapy: Female 6; Male 7 CBT: Female 10; Male 9 One-session panic management: Female 11; Male 13 Supportive care as usual: Female 6; Male 9 Age Range 19 to 81 Pharmacotherapy 40.31 (SD 11.74) 7-session CBT 46.26 (SD 13.61) 1-session panic management 40.79 (SD 13.73)	PD Severity score on Anxiety Disorder Interview Schedule for DSM-IV (ADIS-IV) Panic and Agoraphobia Scale (PAS) Agoraphobic Cognitions Questionnaire (ACQ) Anxiety Sensitivity Index (ASI) Body Sensations Questionnaire (BSQ) Spielberger State–Trait Anxiety Inventory (STAI) Beck Depression Inventory-Revised (BDI-II) McGill Pain Questionnaire (MPQ) Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)

Intervention details							
Clinical Presentation: Panic and/or Non-cardiac chest pain							
Study ID	**Follow up**	**Intervention Format**	**Intervention content (Key features)**	**Theoretical underpinning**	**Recruitment setting**	**Delivery setting**	**Delivery personnel**
Randomised Controlled Trials							
12	6 months	6 x 45 minute sessions of CBT guided by a manual	CBT for panic and depression, including: psychoeducation, avoidance behaviors, depression cognitive model, cognitive restructuring of the automatic anxiety-provoking or depressive mood-provoking cognitions; behavioral interventions. Treatment adjusted for diagnosis. For patients with panic disorder, with or without agoraphobia, the rationale of exposure in vivo was explained and exposure in vivo homework assignments were given. For patients with depression, reactivation was	Cognitive behavioural	Cardiac Emergency Unit	Outpatient setting	Clinical Psychologists
Clinical studies (Non-RCT)							
13	12 months	Groups received usual care plus: Brochure group - received a brochure & psychiatric referral Contact group - received brochure, psychiatric referral and immediate consultation from someone in the psychistry department about panic (1 x 20-30mins session)	Brochure explained panic disorder, its symptoms and treatment available. Contact group consultation on anxiety management techniques (diaphragmatic breathing or attentional refocusing).	Exposure/Cognitive behavioural	Emergency department	Emergency department	ED personnel or trained educator from psychiatric department
14	1 month & 3 months	1 x 45 minute session	Psychoeducation, behavioural experiments e.g. hyperventilation; instructions on exposure to feared sensations and situations; stress management advice	Cognitive behavioural	Emergency department	Emergency department	Cognitive behavioural therapist
15	3 months & 6 months	1 x 60 minute session of reassurance or reassurance + exposure instruction	Both groups: Patient received reassurance that they had experienced a panic attack and that there not was no psychiatric or phsyical disorder. Exposure instruction group: psychoeducation on exposure therapy and advised to return to the panic-inducing situation and wait until the anxiety reduces.	Cognitive behavioural	Emergency department	Emergency department	Research project Psychiatrist
Case studies							
16	12 months	9 x 1-hour sessions over the course of seven to nine weeks.	Hyperventilation provocation test (HVPT), controlled diaphragmatic breathing training, relaxation training, behavioral-based learning procedures.	Behavioural	Emergency department	Hospital cardiac clinic	Doctoral level graduate students in clinical psychology

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16	12 months	9 x 1-hour sessions over the course of seven to nine weeks.	Hyperventilation provocation test (HVPT), controlled diaphragmatic breathing training, relaxation training, behavioral-based learning procedures.	Behavioural	Emergency department	Hospital cardiac clinic	Doctoral level graduate students in clinical psychology

Study outcomes			
Clinical Presentation: Panic and/or Non-cardiac chest pain			
Study ID	**Key Results**	**Frequent attendance impact**	**Conclusion**
Randomised Controlled Trials			
12	CBT was superior after 24 weeks in reducing disease severity (p<.001) when compared to TAU. Positive effects also seen on: TAU on HAM-D (p<0.001),HADS-A (p< .001) and STAI-T (p<0.001). No significant differences on the HADS-D, STAI-T, and FQ.	N/A	CBT might be indicated for patients with NCCP + panic and/or depressive disorders.
Clinical studies (non-RCT)			
13	Statistically significant decrease in ED usage in contact group (p =0.0017) in comparison to the brochure condition, but not with the control (p=0.0672). Increase in ED use among patients given brochure only.	Contact group had reduced ED attendance. All groups increased attendance in other department s.	Brief psychological intervention, provided imediately might be effective for patients presenting with panic in the ED Brief education useful for in helping patients access panic treatments. Providing a brochure may generate feeling of unmet-need and contribute to repeat ED
14	PDSS-SR scores showed no significant differences between intervention (p=.208) and control (p=.427) at 3-month follow-up. However, when additional CBT was provided, panic symptoms reduced.	N/A	CBT is a useful early intervention in panic disorder. Offer in a stepped-care model.
15	Intervention exposure group improved on measures of depression (p<0.002), avoidance (p<0.003) and panic frequency (p,0.03) over 6-months. Group receiving Reassurance only did not improve and reported worse agoraphobic avoidance in the same time period.	N/A	Patients seeking treatment for panic can benefit from early intervention using exposure instructions
Case studies			
16	Decrease in the intensity and frequency of chest pain episodes and in the frequency of shortness of breath episodes in all participants (n=3). Maintenance at 1-year follow-up was seen in two participants.	Participants (n=3) had minimum of 3 visits p/a prior to intervention . Post intervention : 0 visits p/a	Hyperventilation related chest pain can be treated using behavioural approach in the ED.

Studies excluded on age (but included here for completeness & discussion)							
17	1 month & 3 months	Brief CBT 1 x 60 minute session Follow-up by mail	Based on panic control treatment: psychoeducation, diaphragmatic breathing, cognitive restructuring	Cognitive-behavioural	Emergency department	Cardiac inpatient unit	Cardiac nurse
18	6 months & 12 months	4-10 sessions of CBT	Modification of CBT for heath anxiety (formulation, identifying maintaining factors, relapse prevention planning). Where health anxiety was part of the presentation, content focussed on other underlying fears and worries.	Cognitive-behavioural	Cardiology clinics, acute medicine and/or accident and emergency departments	Cardiology clinics	Nurses and psychologists
19	3 months, 6 months (& 12 months - see Marchand)	PMI: 1 x 2 hour session panic management intervention CBT: 7 x 1 hour biweekly CBT session	PMI group: information and education on chest pain, panic attacks, PD and agoraphobia & development and the maintenance of PD; demystification of panic symptoms, cognitive restructuring and strategies to cope with panic. Self-management manual given. CBT group: As 1-session PMI plus exposure to physical sensations related to panic symptoms and in-vivo exposure (when applicable). Participants given same self-management manual as	Cognitive behavioural	Emergency department	Emergency department	Psychologist
20	3 months, 6 months (& 12 months - see Marchand)	Drug group: Generic paroxetine for 6 months, with regular medical follow-ups. CBT: 7 x 1 hour biweekly CBT session	CBT group: psychoeducation; exposure to panic symptoms; in vivo exposure to avoided situations (if applicable); cognitive restructuring.	Cognitive behavioural	Emergency department	Emergency department	Psychologist
21	N/A	7 x 1-h sessions of CBT using manualised approach 1 x 2 hour session of Panic Management CBT using a manualised approach	7 x 1 hr CBT Psychoeducation, demystification of panic symptoms, in vivo exposure, cognitive restructuring. Manual given to all patients. 1 x 2hr Panic Management Management of panic symptoms (PM). With the exception of exposure to physical sensations and in vivo exposure, the same strategies as those in the seven-session intervention were used, but were delivered in a single session. Manual given to all patients. Pharmacotherapy Paroxetine 10 mg gradually increased to 40 mg - dose was maintained for 4 months and then gradually tapered down over a 4-week period (over 6-month period.) Supportive usual care. No active intervention but received a series of follow-	Cognitive behavioural	Emergency department	Emergency department	CBT: Clinical Psychologist or Emergency physician (pharmacotherapy group)

	Studies excluded on age (but included here for completeness & discussion)		
17	CBT group demonstrated a greater decrease in frequency of chest pain episodes, anxiety sensitivity, and fear of cardiac symptoms at 1- and 3-month follow-up (p=0.02). No differences on chest pain severity, cardiac-related avoidance or attention, quality of life, or general psychological distress.	N/A	Patients with NCCP may benefit from a brief CBT intervention delivered in a medical setting
18	No significant group differences between any of the outcome measures at either 6 months or 12 months, patients receiving CBT-CP had between two and three times fewer hospital bed days, outpatient appointments, and A&E attendances than those allocated to standard care and total costs per patient were £1496.49 lower (non-significant difference). There was a small non-significant gain in quality adjusted life years in those allocated to CBT-CP compared with standard care (0.76 vs 0.74).	Participants in the CBT group had less than half as many outpatient appointments and A&E attendances as those in the standard care group	CBT-CP could be a cost-effective treatment for NCCP. Changes in service configuration, mental health literacy in hospitals and a different recruitment strategy are needed. An integrated service to assess both medical and mental pathology is required.
19	Significant reduction in panic disorder severity following both interventions compared to usual care control condition (p =.05). Neither intervention showed superiority compared to the other.	N/A	A brief CBT-based intervention initiated within 2 weeks of ED visit for chest pain appear to be effective for PD.
20	Both interventions demonstrated significant reductions of PD severity (p= .012), frequency of panic attacks (p= .048), and depressive symptoms (p= .027).	N/A	Interventions for PD initiated in an ED setting can be feasible and efficacious, and future studies should assess their impact on both the direct (ie, health care utilization) and indirect (ie, lost productivity) costs associated with PD morbidity in this population.
21	Across all interventions, PD severity improved after treatment over time (p<.001) but no significant difference between conditions (p=.095). Interventions more effective for PD severity than usual care. On the other measures, patients improved in all conditions, and the therapeutic gains were maintained up to 1 year following the visit to the ED.	N/A	Early intervention, in particular seven sessions of CBT, one session of PM or pharmacotherapy (generic paroxetine), should be considered for the treatment of PD patients consulting the ED with a diagnosis of NCCP

Study characteristics						
Clinical Presentation: Trauma/PTSD Prevention						
Study ID	**Author & Year**	**Title**	**Design**	**Sample**	**Characteristics of participants Gender & Mean Age (SD)**	**Key measures**
Randomised controlled trials						
1	Bugg (2007) UK	A randomised controlled trial of the effectiveness of writing as a self-help intervention for traumatic injury patients at risk of developing post-traumatic stress disorder	RCT	148 participants Two groups: Writing group (n=72) Information group (n=76)	Gender Writing group: Female 28/31 (90.3%); Male 3/31 (9.7%) Information group: Female 20/36 (55.6%); Male 16/36 (44.4%) Age Writing group: 36.65 (SD 13.47) Information group: 38.14 (SD 12.49)	Post-traumatic Diagnostic Scale (PDS) Hospital Anxiety and Depression Scale (HADS)
2	Brunet, A. et al. (2013). Canada	Randomized controlled trial of a brief dyadic cognitive-behavioral intervention designed to prevent PTSD	RCT	83 participants Two groups: Intervention group (n=44) Control group (n=39)	Gender: Intervention group: Female: 20 (54%); Male: 17 (46%) Control group: Female: 14 (38%); Male 23 (62%) Age: Intervention group: 37.97 (SD 12.58); Control group: 34.68 (9.16)	Impact of Event Scale-Revised (IES-R)
3	Des Groseilliers et al. (2013) Canada (NB This is follow-up of Brunet et al. 2013, above)	Two-year follow-up of a brief dyadic cognitive-behavioral intervention designed to prevent PTSD	Follow-up study	46 participants (70% of original study). Two groups: Intervention group (n=26), Repeated assessment control group (n=20)	Gender Intervention: Female 15 (58%); Male 11 (42%) No intervention: Female 9 (45%); Male 11 (55%) Age Intervention group: 39.32 (SD 12.58) No intervention group: 35.35 (SD 9.24)	As above
4	Iyadurai, L.. et al. (2018) UK	Preventing intrusive memories after trauma via a brief intervention involving Tetris computer game play in the emergency department: a proof-of-concept randomized controlled trial	RCT	71 participants Two groups: intervention group (n=37) and control group (n=34)	Gender: Intervention: Female: 20 (54.1%); Male: 17 (45.9%) Control: Female: 17 (50%); Male: 17 (50%) Age: Intervention: 38.9 1(SD 16.1) Control: 40.5 (SD 16.8)	Total no. of intrusive memories in the week after the traumatic event self-report Impact of Event Scale-Revised; Post-traumatic Diagnostic Scale (PDS) Hospital Anxiety and Depression Scale (HADS)
5	Scholes et al.(2007) UK	A randomised controlled trial to assess the effectiveness of providing self-help information to people with symptoms of acute stress disorder following a traumatic injury	RCT	411 participants Three groups: High risk intervention HI (n=116) High risk control - HC (n=111) Low risk control - LC (n=120).	Gender: HI: Female: 66 (56.9%); Male: 50 (43.1%) HC: Female: 51 (45.95%); Male: 60 (54.05%) LC: Female: 39 (32.5%); Male: 81(67.5) Age: HI: 37.62 HC: 35.61 LC: 38.55	Post-traumatic Diagnostic Scale (PDS) Hospital Anxiety and Depression Scale (HADS)
6	Turpin et. al. (2005) UK	Effectiveness of providing self-help information following acute traumatic injury: Randomised controlled trial	RCT	291 participants Two groups: intervention (n=146) control (n=145)	Gender Intervention: Female 34 (45%) ; Male 41 (55%) Control: Female: 36 (54%); Male 31 (46%) Age Intervention 39.74 (SD 12.48) Control 37.42 (SD 12.13)	Post-traumatic Diagnostic Scale (PDS) Hospital Anxiety and Depression Scale (HADS)
7	Wu, K. (2014) China	A randomized controlled trial of the effectiveness of brief-CBT for Patients with symptoms of posttraumatic stress following a motor vehicle crash	RCT	60 participants Two groups: B-CBT group (n=29) Self-help group (n=31)	Gender: Intervention B- CBT group: Female: 7 (28%); Male: 18 (62%) Self-help group: Female 10 (35.7 %); Male: 18 (64.3%) Age: Intervention B-CBT group: 35.72 (SD 11.32);	Impact of Event Scale-Revised (IES-R) Hospital Anxiety and Depression Scale (HADS)

Clinical studies (Non-RCT)						
8	Rothbaum et al. (2012) USA	Early intervention may prevent the development of posttraumatic stress disorder: A randomized pilot civilian study with modified prolonged exposure	Randomised pilot study	137 participants Two groups: Intervention group (n=69) Assessment only group (n=68)	Gender Assessment group: Female: 45 (66.20%); Male: 23 (33.80%) Intervention group: Female: 44 (63.80%); Male: 25 (36.20%) Age Intervention group: 30.17 (SD 12.08) Assessment group: 32.78 (SD 11.12)	PTSD Symptom Scale-Interview Version (PSS-I) Beck Depression Inventory(BDI) Posttraumatic Stress Diagnostic Scale(PDS)
9	Rothbaum et al. (2008) USA	A pilot study of an exposure-based intervention in the ED designed to prevent posttraumatic stress disorder	Non randomised pilot study	10 participants Two groups: Intervention group (n=5) Assessment only group (n=5)	Gender: Assessment group: Female: 5 (100%) : Male: 0 (0%) Intervention group: Female: 2 (40%); Male: 3 (60%) Age: Assessment group: Female: 26.4; Male: n/a Intervention group: Female: 42; Male: 40.7	PTSD Symptom Scale-I (PSS) PTSD Diagnostic Scale (PDS) Beck Depression Inventory (BDI) State-Trait Anxiety Inventory (STAI) Clinical Global Improvement Scale (CGI)
Case studies						
10	Post, Loren M. et al. (2017) USA	Psychological and psychobiological responses to immediate early intervention in the emergency department: Case report of one-session exposure therapy for the prevention of PTSD	Case study	1 participant	Gender: Female Age:23	Psychological: PTSD Symptom Scale (PSS) Beck Depression Inventory (BDI) Psychobiological: Skin conductance (SC) fMRI - go/no-go task to assess behavioural inhiibition Fear Potentiated Startle (FPS) paradigm to assess startle response
Studies excluded on age (but included here for completeness & discussion)						
11	Zatzick (2015) USA	Technology-Enhanced Stepped Collaborative Care Targeting Posttraumatic Stress Disorder and Comorbidity After Injury: A Randomized Controlled Trial	RCT	121 participants Two groups: Intervention group (n=60) Usual care group (n=61)	Studies age inclusion criteria: age 14 years + Gender Intervention group: Female 21 (35%), Male 39 (65%) Usual care group: Female 22, (36.1%), Male 39 (63.9%) Age Intervention group: 42.80 (14.65) Usual care group: 43.52 (14.84)	Post-traumatic disorder checklist (PCL-C) Patient Health Questionnaire-9 Depression (PHQ-9)

Intervention details						
Clinical Presentation: Trauma/PTSD Prevention						
Study ID	Intervention Format (Key details)	Intervention content (Key features)	Theoretical underpinning	Recruitment setting	Delivery setting	Delivery personnel
Randomised controlled trials						
1	Writing intervention group 1 x 1 hour appointment to receive instructions for writing and completed a 20-min writing exercise followed by the post-writing questionnaire. Participants then completed two further writing sessions at home on consecutive days. Pre and post questionnaires used.	Self help book: Contained information on the symptoms of traumatic stress and advice on strategies for recovering. Writing intervention: Participants wrote about their deepest emotions, thoughts and feelings relating to their accident or injury for 20 min.	Exposure theory; schematic processing theory;	Emergency department	Home (self-help)	Trainee Clinical Psychologist
2	Two-session manualised intervention. Duration: 90 min & 75 min. Control - no intervention, questionnaires only.	This two-session manualized dyadic cognitive-behavioral intervention It includes elements of psychoeducation, coping skills training, and motivational interviewing and targets communication between the patient and significant other. other, aiming to facilitate bidirectional disclosure and reduce disclosure-constraining behaviors.	Social-cognitive processing; cognitive behavioural, motivational interviewing	Emergency department	Hospital	Social worker or nurse
3	This study is a follow up of the original intervention (above). Participants completed a 2-hour audiotaped clinical interview at the psychiatric hospital or at thei patient's home. Participants also filled out several self-report questionnaires in French or in English.	As above	As above	N/A follow up	N/A follow up	Research assistant
4	Intervention: a reminder cue for the traumatic event followed by playing Tetris. Duration: Tetris game play time for at least one uninterrupted period of minimum of 10 min and for ~ 20 min in total. Control: Participants filled a pen & paper log of activity they had engaged in withn the ED. Duration: similar to intervention condition.	Tetris is a video game with high visual-spatial demands	Neuropsychological: memory consolidation theory; cogntive theory (cognitive task completion)	Emergency department	Emergency department	Clinical Psychologist
5	Eligible patients contacted and consented by post. Eligible patients randomly assigned to two groups: high-risk intervention (HI) and high-risk control (HC). Non-eligible patients were allocated to a low-risk control group (LC). Participants sent questionnaires within 1 month of their accident. The HI group were also sent the self-help booklet and instructed to complete the questionnaires before reading the booklet. Follow-up questionnaires sent at 3 and 6 months after their accident.	Self help book contained information about the psychological sequelae of trauma and structured proactive advice based on cognitive behavioural strategies	Cognitive behavioural	Emergency department	Home (self-help)	Trainee Clinical Psychologist
6	Consent and questionaire sent out by post. Intervention group sent a self-help booklet. Control group sent a letter without the patient information. Four weeks later all participants sent a second questionnaire to assess differences in psychological outcome. A follow-up questionnaire sent to both groups between 24 and 26 weeks following attendance. Control participants offered a copy of the self-help booklet at the end of the study.	Self-help book contained information on common physiological, psychological and behavioural reactions to traumatic injury, advice regarding non-avoidance and emotional support, information on seeking further help.	Cognitive behavioural	Emergency department	Home (self-help)	Trainee Clinical Psychologist
7	B-CBT 4 x 1.5 hour weekly session. Manualised therapy.	B-CBT: Psychoeducation, rationale of exposure-based CBT, imaginal exposure, Image habituation training (if indicated), cognitive distortions discussed, graded in-vivo exposure. Homework practice was included. Self-help: Psychoeducation, rationale for exposure exercises, cognitive processing, relaxation exercises. Homework practice was included	Cognitive behavioural	Emergency department	Clinical psychology outpatient department	Clinical Psychologist

		Clinical studies (Non-RCT)				
8	Initial assessment then random assignment to either intervention or assessment-only groups. Intervention provided immediately. Patients received 3 x 1 hour sessions of a modified PE intervention, distributed 1 week apart. Intervention included homework assignments. Follow-up assessments completed at 4-weeks, 12-weeks and 3-months.	Session 1 Introduction, imaginal exposure, psychoeducation, behavioural exposure homework setting, breathing re-training Session 2 Imaginal exposure, behavioural exposure homework setting, self-care Session 3 Imaginal exposure, behavioural exposure plannign for post-intervention, self-care planning.	Neuroscientific theory: memory consolidation theory; Exposure theory	Emergency department	Emergency department	Trained therapists
9	Intervention: 1-session abbreviated imaginal exposure intervention (duration not stated). Follow-up in ED 1 week later.	Intervention included: giving verbal and written information about reactions to trauma, rational for exposure, and abbreviated imaginal exposure intervention.	Neuroscientific theory: memory consolidation theory; Exposure theory	Emergency department	Emergency department	Research clinicians (supported by ED staff)
		Case studies				
10	1 session Duration: 1 hour plus homework task	In-session Imaginal exposure, reframing, behavioural exposure homework setting, psychoeducation, breathing re-training exercises, homework review Homework: listen to audio recording of imaginal exposure; practice positive self-statements, behavioural exposure, self-care, breathing re-training	Neuropsychological: memory consolidation theory; Exposure theory	Emergency department	Emergency department	Therapist
		Studies excluded on age (but included here for completeness & discussion)				
11	Duration: Ongoing care over 6 months, IT element had a median duration of 2.25 hours per patient. Intervention participants given a laptop and guidance on web and smartphone applications. Care manager collaborately developed a treatment plan with patient. Patients stepped up as clinically indicated. A computerised clinical decision support tool was also used. Usual care group: Usual care (routine outpatient surgical, primary care, and ED visits, and mental	Stepped measurement-based intervention stepped collaborative care intervention elements included postinjury care management and pharmacotherapy, motivational interviewing (MI), and CBT elements embedded within routine care management CBT element included: problem solving, psychoeducation, anxiety reduction techniques such as training in progressive muscle relaxation and breathing, attention to experience, and exposure-based and	Cognitive behavioural	Medical Centre Level I trauma centre inpatient surgical ward or Emergency Department	Medical Centre Level I trauma centre inpatient surgical ward or Emergency Department	Doctoral-level care management and behavioral therapists & medical pharmacotherapists

Study outcomes				
Clinical Presentation: Trauma/PTSD Prevention				
Study ID	**Follow-up**	**Key Results**	**attendance impact**	**Conclusion**
Randomised controlled trials				
1	3-month & 6 month	Results were non-statistically significant	N/A	Writing intervention for PTSD-prevention following traumatic injury is not effective.
2	21 days, 35 days, 3 months & 2 years (see below)	Controlling the improvement in controls lead to an effect size of d = 0.39 in the intervention.	N/A	Brief intervention can be effective for ED patients post- trauma
3	N/A	Decreased in self-reported PTSD symptoms (IES-R) in the treated group at 2-year follow-up when compared with the control group (p0.008).	N/A	Trauma survivors imay benefot from intervention for PTSD-prevention.
4	1 week & 1 month	Fewer intrusive memories were recorded by intervention participants 1-week post accident when compared to controls (p=0.005, d=0.67). 1-week follow-up showed that intervention participants had lower distress caused by intrusions in comparison to controls (d=0.54). Small to negligible effect sizes were found for all other measures at follow-up.	N/A	Tetris-based intervention delivered post-trauma effective for rducing intrusive memories of trauma over 1 week.
5	3-month & 6 month	Decrease in PTSD, anxiety and depression (p <0.001) across time. No group differences in these or quality of life measures.	N/A	Patients valued self-help information. Study results do not support the efficacy of providing self-help information for PTSD-prevention
6	6 -6.5 months	Decrease in PTSD anxiety and depression (p<0.05) over time. No group differences in PTSD or anxiety. Control group was less depressed (p<0.05) at follow-up. Reduction in PTSD caseness in controls (50%) compared with the intervention (20%), close to significance (p<0.06).	N/A	Patients valued self-help information. Study results do not support the efficacy of providing self-help information for PTSD-prevention
7	3-month & 6 month	B-CBT group: greater reductions in anxiety at 3-month and 6-month follow-up. Also, reduced depression at 6-month follow-up. Higher pretreatment anxiety and depression predicted negative outcome at 6-month follow-up in self-help group. No differential effect on PTSD symptoms (IES-R).	N/A	B-CBT may be an effective preventive intervention following motor vehicle crash

		Clinical studies (Non-RCT)		
8	1 month & 3 months	Significantly lower PTSD symptoms in the intervention group at 4 weeks postinjury (p .01) . Improvements also seen at further follow-up: 12 weeks postinjury (p .05). Significantly lower depression seen at week 4 compared to the assessment group (p .05). The intervention was the most effective in PTSD reduction in rape victims at week 4 (p .004) and week 12 (p.05).	N/A	Intervention is safe and feasible Intervenion successful at reducing PTSD and depression symptoms at 1 and 3 month follow-up post trauma.
9	1 week	Trend towards decreased depression (BDI) in the intervention group (pre-to-post treatment) and in addition, a decrease in clinician-rated symptom severity was found at at 1-week follow-up. Trend towards increased depression in the assessment group, plus non-significant increase in anxiety from pre-to post assessment.	N/A	Intervention is safe and feasible and may be helpful.
		Case studies		
10	1 month & 3 months	Post intervention, participant did not display symptom worsening or develop PTSD even though risk factors had been apparent.	N/A	Intervention may be effective for PTSD-prevention
		Studies excluded on age (but included here for completeness & discussion)		
11	1, 3 & 6 months	Modest but non-significant symptom reductions (p = .055) in intervention group. Significant result on covariate adjusted regression (p = .049). PTSD intervention effect was greatest at the 3-month (d = 0.35, p = .044) and 6-month (d = 0.38, p = .044) time points.	N/A	IT-enhanced care could help to deliver PTSD treatment after injury

Study characteristics

Clinical Presentation: Other - 'Medically Unexplained' Symptoms, Health Anxiety, Health Behaviour Change

Study ID	Author & Year	Title	Design	Sample	Characteristics of participant Gender & Mean Age (SD)	Key measures
Randomised controlled trials						
22	Katz et al. (2017) USA	Multiple Risk Factor Counseling to Promote Heart-healthy Lifestyles in the Chest Pain Observation Unit: Pilot Randomized Controlled Trial	RCT	140 participants Two groups Full intervention: n=70 Partial intervention:n=70	Full intervention Female 51%; Male 49% Partial intervention: Female 49% Male 51%	Health beliefs Health Motivation Assessment Inventory subscale (HMAI) Osteoporosis Health Belief Scale (OHBS) (modified) Cardiac Dietary Self Efficacy Index (CDSEI) Brief measure of exercise self-efficacy Smoking Self-efficacy Questionnaire (SEQ-12) Measures of stages of change for diet, exercise, smoking cessation. Cardiovascular risk behaviours rapid food screening survey Physical Activity Recall scale (PAR) Smoking behaviours
Clinical studies (Non-RCT)						
23	Abbass et. al. (2009) Canada	Intensive short-term dynamic psychotherapy to reduce rates of emergency department return visits for patients with medically unexplained symptoms: preliminary evidence from a pre-post intervention study	Pre-post intervention study	50 participants	Gender Female 35 (70%); Male 15 (30%) Age All 36.9 (SD 14.0)	ED usage data Brief Symptom Inventory (BSI)
Case studies						
24	Daniels & Sheils (2017) UK	A Complex Interplay: Cognitive Behavioural Therapy for Severe Health Anxiety in Addison's Disease to Reduce Emergency Department Admissions	Case study (A/B design)	1 participant	Female, aged 40s	Health Anxiety Inventory (HAI) Patient Health Questionnaire (PHQ-9) Generalized Anxiety Disorder (GAD-7) ED usage data

Intervention details

Clinical Presentation: Other - 'Medically Unexplained' Symptoms, Health Anxiety, Health Behaviour Change

Study ID	Intervention Format	Intervention content (Key features)	Approach/Theoretical underpinning	Recruitment setting	Delivery setting	Delivery personnel
Randomised controlled trials						
22	Maximum counselling 1 x 1 hour counselling + handout 2 x 30 minute follow up session 1 x follow-up phone call Minimal counselling Brief counseling (<5 minutes) + handout	Maximum counselling: Each patient had a personalised risk factor report. Counselling for specific risk factors included: nutrition, physical activity and smoking cessation assessment. Follow-up session: review behavior change priorities, develop a change plan, develop problem solving skills. Follow-up phone call: review progress and address concerns. Patients also received a self-management handout. Minimal counselling: Brief counseling (<5 minutes) on the benefits of changing lifestyle and given the same self-management handout. In addition, patients were mailed the personalised cardiovascular risk assessment report described above at the end of 6-month follow-up.	Counselling/Health belief model	Chest pain observation unit (CPOU) of an academic emergency department (ED)	Chest pain observation unit (CPOU) of an academic emergency department (ED)	Health Educator
Clinical studies (Non-RCT)						
23	All patients were assessed and then attended a psychodiagnostic and evaluative interview. Some patients then had additional sessions (2 sessions (n=15); more than 2 sessions (n=15)).	Link between emotional activation and physical effects; identifying and experiencing emotions; somatic effects of emotional dysregulation; the impact on the body and on cognitive perceptual functioning of unconscious components of anxiety; anxiety tolerence techniques.	Psychodynamic	Emergency Department	Emergency department quiet rooms or in hospital	Emergency practitioner
Case studies						
24	12 x 1 hour sessions of CBT	CBT for health anxiety: psychoeducation, formulation, identifying and challenging beliefs, developing alternative explanations for physical sensations, behavioural experiments, developing coping strategies and a self-management	CBT	Emergency Department	Clinic attached to an acute hospital ED	Clinical Psychologist

Study outcomes				
Clinical Presentation: Other - 'Medically Unexplained' Symptoms, Health Anxiety, Health Behaviour Change				
Study ID	**Follow-up**	**Key Results**	**Frequent attendance impact**	**Conclusion**
Randomised controlled trials				
22	2 months & 6 months	The groups showed no signficant differences in measures of cardiovascular health beliefs, readiness to change, or CRF-related behaviors at follow-up.	N/A	Risk factor-related intervention for increasing motivation to change was not effective however patients demonstrated sustained changes in cardiovascular health beliefs and risk-related behaviors at follow-up.
Clinical studies (Non-RCT)				
23	12 months	Significant improvements seen in >2 sessions (p< 0.01) on the somatisation subscale (p=0.02) and on the BSI global rating scale.	69% (3.2, SD 6.4) ED visit per patient reduction (p < 0.001)	Patient feedback (n=13) suggested satisfaction with the intervention. ISTDP diagnostic and treatment services appear to be effective for somatisation-related MUS.
Case studies				
24	12 months	Reliable, clinical change seen across all measures, pre to post.	Pre= 6 visits p/a; Post=0 visits p/a	CBT helpful for Addison's Disease plus health anxiety where ED usage is impacted

Appendix C - Service Improvement Project: Target Journal Guidance for Authors

British Journal of Obesity. Details available at:

http://www.britishjournalofobesity.co.uk/authors

CALL FOR PAPERS

Would you like to write for the *British Journal of Obesity*? If so, we want to hear from you

To submit an article online, please visit: http://www.epress.ac.uk/bjo/webforms/author.php
If you have any queries, please contact bjo@sbcommunicationsgroup.com

Article types
Articles may fall into the following categories. All articles should be 1700–2300 words in length and written with consideration of the journal's readership (general practitioners, practice nurses, dietitians, psychologists, bariatric surgeons and other healthcare professionals with an interest in obesity).

Clinical reviews should present a balanced consideration of a particular clinical area, covering the evidence that exists. The relevance to practice should be highlighted where appropriate.

Original research articles should be presented with sections for the background, aims, methods, results, discussion and conclusion. The discussion should consider the implications for practice.

Clinical guideline articles should appraise newly published clinical guidelines and assess how they will sit alongside existing guidelines and impact on the management of obesity.

Organisational articles could provide information on newly published organisational guidelines or explain how a particular local service has been organised to benefit people with obesity.

Title page
Please include the article title, the full names of the authors and their institutional affiliations, as well as full details of each author's current appointment. This page should also have the name, address and contact telephone number(s) of the corresponding author.

Article points and key words
Four or five sentences of 15–20 words that summarise the major themes of the article. Please also provide four or five key words that highlight the content of the article.

Abstract
Approximately 150 words briefly introducing your article, outlining the discussion points and main conclusions.

Introduction
In 60–120 words, this should aim to draw the reader into the article as well as broadly stating what the article is about.

Main body
Use sub-headings liberally and apply formatting to differentiate between heading levels (you may have up to three heading levels). The article must have a conclusion, which should be succinct and logically ordered, ideally identifying gaps in present knowledge and implications for practice, as well as suggesting future initiatives.

Tables and illustrations
Tables and figures – particularly photographs – are encouraged wherever appropriate. Figures and tables should be numbered consecutively in the order of their first citation in the text. Present tables at the end of the articles; supply figures as logically labelled separate files. If a figure or table has been published previously, acknowledge the original source and submit written permission from the copyright holder to reproduce the material.

References
In the text
Use the name and year (Harvard) system for references in the text, as exemplified by the following:
- As Smith and Jones (2003) have shown …
- As already reported (Smith and Jones, 2003) …

For three or more authors, give the first author's surname followed by et al:
- As Robson et al (2005) have shown …

Simultaneous references should be ordered chronologically first, and then alphabetically:
- (Smith and Jones, 2003; Young, 2003; Black, 2004).

Statements based on a personal communication should be indicated as such, with the name of the person and the year.

In the reference list
The total number of references should not exceed 30 without prior discussion with the Editor. Arrange references alphabetically first, and then chronologically. Give the surnames and initials of all authors for references with four or fewer authors; for five or more, give the first three and add "et al". Papers accepted but not yet published may be included in the reference list as being "[In press]".

Journal article example: Robson R, Seed J, Khan E et al (2005) Diabetes in childhood. *Diabetes Journal* 9: 119–23

Whole book example: White F, Moore B (2004) *Childhood Diabetes*. Academic Press, London

Book chapter example: Fisher M (2002) The role of age. In: Merson A, Kriek U (eds). *Diabetes in Children*. 2nd edn. Academic Press, London: 15–32

Document on website example: Department of Health (2003) *National Service Framework for Diabetes: Delivery Strategy*. DH, London. Available at: http://www.dh.gov.uk/assetRoot/04/03/28/23/04032823.pdf (accessed 01.03.11)

Appendix D – Service Improvement Project: Balance Course Content

Balance course content included dietetic, psychological and behavioural elements, with topics including:

- Setting goals
- Motivation and commitment to change
- Compassion and forgiveness
- Mindful eating, focus and domino foods
- Finding meaning and vitality in life
- Establishing peer support
- Feelings and food
- Food fables
- Psychological flexibility and acceptance
- Preventing relapse and wellness for life
- The importance of regular eating
- Diet myths
- The Eatwell Plate
- Metabolism & appetite
- The binge-starve cycle
- Portions
- Snacking and craving
- Food labels
- Food groups fats, sugars
- Exercise and activity

Appendix E – Service Improvement Project: Balance End of Course Questionnaire

The attendees were asked to complete an anonymous questionnaire upon finishing the course. The questionnaire has both closed and open questions.

Quantitative results

QUESTION	EXCELLENT	VERY GOOD	AVERAGE	POOR	VERY POOR
Overall how would you rate the course?	80 %	20%	0%	0%	0%

QUESTION	EXCELLENT	GOOD	AVERAGE	POOR	VERY POOR
Overall how would you rate the course facilitators?	82%	18%	0%	0%	0%

QUESTION	YES	NO
Would you recommend this course to a friend or family member?	100%	0%

11 people completed this questionnaire. N.B. the qualitative data in this questionnaire has been summarised into themes, formal thematic analysis on this data has not been used due to there being small amount of data.

N.B. Where the answer given did not respond to the question asked, these comments have been included under the "Other" comments section.

Qualitative feedback on content of sessions

"Thinking about all the session in Balance, which were the ones which you found least informative, or didn't lead to any change?"

- No or no comment (7 people said this)
- "They were all valuable / very useful / informative and helpful (3 people)
- "The quiz, but still good fun as a mid-way session" (1 person)

"Do you think these sessions could be changed to make them better or could they be removed completely?"

- No or no comment (8 people)
- It was all helpful / we all benefitted from it (3 people)

"Was there something missing from the course? Or something you would have liked more of?"

- No or no comment (7 people)
- Yes: More about cooking would be good and more about the importance of using workbooks between sessions. (1 person)
- Yes: Perhaps more of a reminder about the "Get Ready For Change" course (1 person)

“If you mention Balance to friends of family members, what do you say about it?”

“I say that it's an in-depth approach to weight loss unlike commercial firms such as Weight Watchers or Slimming World”.
“Very informative and focused, non-judgmental, helpful, not just a quick fix diet but its' information and coping skills make it a long term healthy eating choices”
“I say I enjoyed it so much that I would like to repeat it again or at least be allowed to sit in on another course the sessions that I missed.”
“I don't need to say anything, my friends and family can see the difference in me. I know of at least 3 people who would like to come on the course it it becomes available.”
“It now makes me think about why eating and it's OK to eat, not to beat yourself up about eating”.
“It's changed my life - changed my whole outlook on 'dieting' but also helped with other areas of life too”
“I have had conversations with people attending Slimming World about this course. It's an education rather than a diet course.”
“It gives perspective on emotional/physical and nutritional aspects, needing to be kinder to yourself. Seeing other peoples' journeys.”
“It creates an attitude of mind”
“Weight management that helps with not eating when stressed and de-align with emotional eating”

Table 9: Reports to Family and Friends

“Please add any further comments here”:

There were three themes within the further comments: keep running this course; the course has helped me and practical suggestions for developing the course. N.B. the qualitative data in this questionnaire has been summarised into themes, formal thematic analysis on this data has not been used due to there being small amount of data.

Theme 1: Keep it going

“I would hate to think that this course could be removed completely. In fact, I missed 3 of the sessions and I would like to think that I could come to these again.”

“Everyone should have the chance to attend a course like this, especially younger people, maybe school age to understand and stop bad habits forming.”

“Really thank you so much. Please don't stop doing it. I was in a really bad place to start and now using the Facebook group to reduce alcohol setting goals of no drinking in the week - DID IT! The Facebook group is a safe place to say 'I've ballsed up' and people will be kind.'”

“Just for it to continue!” (1 person)

Theme 2: This has helped me

“I am very grateful for this course - has made a massive difference for me.”

“I have dropped a dress size during the course.”

“Nice relaxed atmosphere. Easy to take part in discussions.”

Theme 3: Suggestions

Questionnaires: “Some frustration with the questionnaires used in the course - PHQ9 encourages focus on the negative and the UKDDQ did not allow to give an accurate reflection of my diet. My feedback could not be 100% accurate in this questionnaire because of inflexibility in the questions.”

Being weighed: “I stopped choosing to be weighed as was not losing weight due to significant family stresses, the choice to weigh was good and did not make it reminiscent of WW's or SW. Once I stopped worrying, this was better.”

Follow-up: “A monthly follow-up with weighing would be appreciated.”

Feedback on Course Content

Question 1: “Thinking about all the sessions you had in Balance which were the ones which you found most useful?”

How this question was scored

All 11 participants were asked an open question about what they thought were the most useful sessions. Some participants named particular sessions and others gave a qualitative comment. Where the session included more than one topic, the topic most frequently mentioned by participants is stated in the table below.

Three sessions were mentioned by 6 participants as being the most helpful:

- Session 2 on myths and the Eatwell Plate
- Session 3 on the dieting cycle, specifically information on hormones.
- Session 5 on mindfulness.

SESSION	FREQUENCY MENTIONED
Session 1: Introduction	1
Session 2: Motivation and commitment - Myths; Eatwell Plate	6
Session 3: - Dieting cycle; hormones (ghrelin/leptin)	6
Session 4: - What causes us to become overweight?	4
Session 5: - Using Mindfulness to Change the Way We Eat	6
Session 6: - Emotional Eating	4
Session 7: - Reviewing Progress; Quiz & group discussion	1
Session 8: Assertiveness	4
Session 9 - Secret Eating	1

Session 10 - Social contagion; eating out, takeaways, alcohol	3
Session 11 - Minds (Thoughts v facts; Rules for living; Behavioural experiments)	1
All of it	2

Table 10: Feedback on most useful sessions

Question 2: *"What was it about these sessions which you felt help you to make changes, or what sticks in your mind?"*

9/11 people responded to this question. There were three themes among the comments: the overall helpfulness of the course, benefits of mindfulness, and drawing attention to exercise, nutrition and eating habits.

Theme 1: Overall usefulness

"All the sessions were very interesting and I learnt something new at each session I was able to attend."

"I found all the sessions very useful and they all blended in well with each other, and it's hard to highlight the best as they were all so helpful. The mindfulness and being kind to myself has had a big impact on me."

Theme 2: Using mindfulness

"To be able to use mindfulness rather than being stressed about my weight."

"Change to eating mindfully, mindful eating experiment with Bournville Chocolate."

"Mindfulness is what sticks in my mind the most."

Theme 3: Eating, nutrition and exercise habits

“Reminded me that wasn't doing any exercise.”
“Trying to fit in exercise every day.”
“Eating and exercise - if you overeat, you must exercise.”

“More conscious of eating habits.”

“The importance of nutrition and how healthy eating can be enjoyable. I was living off healthy convenience food and now really enjoying cooking e.g. soups with beautiful veg. Also finding veg are reasonably priced.”

“The most enlightening and helpful was the diet and food elements. I cannot believe I was putting so much rubbish into my body!”

“Realising you can get into terrible habits and not realise until you share with the group. This really helped with making changes. Finding the difference between being on a diet and healthy eating and how 'healthy eating' is often seen as 'diet'. Know it doesn't have to be about denial.”

Appendix F – Service Improvement Project: Gap Analysis (Balance course content comparison with NICE guidelines)

NICE Guidelines: Weight management: lifestyle services for overweight or obese adults NICE guidelines PH53 Weight management: lifestyle services for overweight or obese adults (2014)	**Was this included in Balance?**
Programme elements are multi-component that is, they address dietary intake, physical activity levels and behaviour change.	Yes
Are developed by a multidisciplinary team. This includes input from a registered dietitian, registered practitioner psychologist and a qualified physical activity instructor.	Yes, dietician and psychologist was involved. A physical activity instructor did not provide input.
Ensure staff are trained to deliver them and they receive regular professional development sessions.	Yes
Focus on life-long lifestyle change and the prevention of future weight gain.	Yes
Last at least 3 months, and that sessions are offered at least weekly or fortnightly and include a 'weigh-in' at each session.	Yes
Ensure achievable goals for weight loss are agreed for different stages – including within the first few weeks, for the end of the programme or referral period (as appropriate) and for 1 year (see improve adherence and outcomes in this pathway).	Goal setting and reviewing was optional in Balance

Ensure specific dietary targets are agreed (for example, for a clear energy [calorie] intake or for a specific reduction in energy intake) tailored to individual needs and goals. Note: it is preferable not to 'ban' specific foods or food groups – and the price of any recommended dietary approaches should not be prohibitive. Individual advice from a registered dietitian may be beneficial, but is not essential.	Individual specific dietary targets were not set. Dietician was present at all sessions.
Ensure discussions take place about how to reduce sedentary behaviour and the type of physical activities that can easily be integrated into everyday life and maintained in the long term (for example, walking).	Yes
Ensure any supervised physical activity sessions are led by an appropriately qualified physical activity instructor and take into account any medical conditions people may have. Instructors should be on the Register of Exercise Professionals (or equivalent) at level 3 or above.	N/A physical activity programme was not included
Use a variety of behaviour-change methods. These should address: problem solving; goal setting; how to carry out a particular task or activity; planning to provide social support or make changes to the social environment; self-monitoring of weight and behaviours that can affect weight; and feedback on performance.	Most of these elements were included in Balance. With regards to self-monitoring of weight and behaviours, participants were encouraged to keep food and mood diaries. No one in the focus group mentioned formal energy intake tracking.

	In terms of individual feedback, participants who chose to be weighed were told their weight.
Tailor programmes to support the needs of different groups. For example, programmes should provide men- or women-only sessions as necessary; provide sessions at a range of times and in venues with good transport links or used by a particular community; and consider providing childcare for attendees.	Not applicable, as Balance was a pilot.
Monitor weight, indicators of behaviour change and participants' personal goals throughout the programme.	Weight was monitored at 3 time points (minimum) Personal goals were optional and monitored individually. Sharing goal progress was optional, not formalised. Other indicators of behavior change (e.g. activity levels, energy intake) were not monitored
Adopt a respectful, non-judgmental approach	Yes – focus group participants praised the course philosophy, and the feedback questionnaires noted that the course leaders were supportive.

Appendix G – Service Improvement Project: Commissioner Feedback

"Having Sally complete the SIP on Balance has been invaluable. Firstly, by asking relevant questions about the design and implementation of the service, she helped me to clarify my approach, and be clear about which research it drew upon. This helped to ensure that the design for the pilot were more robust from the start.

Sally also enabled us to hold a focus group which participants could see was separate from the service. I think this will hopefully have lead them to be more open and honest about the service. Focus groups are often very helpful in terms of feedback, but they are not something we regularly get time to do in the service. Having one completed so thoroughly has been a real treat.

In addition, someone with the time and ability to do some more detailed analysis of the measures has been wonderful. For example looking for significance in weight loss and non-parametric statistics around the outcome measures. This is also something that the commissioners have fed back as being interesting.

Finally, it has been really useful to have Sally to discuss recent research in the area and in related fields which can inform the service development as we go in to the next phase. She has been very diligent in sourcing, reading and digesting recent research and feeding this back to us. It is something that we don't always have the time to do (although we always feel we should!) so having someone who can inform us about this has been so incredibly useful."

Feedback from commissioners: Both the Public Health and Mental Health commissioners said that the interim report was extremely helpful for understanding the group and how effective it had been. The Commissioners were particularly grateful for the inclusion of non-parametric statistics. The Weight Management Commissioner noted that s/he would also have liked to see a weight-change line group for each participant, charting their progress over the year. This was added to the final report to service.

Further information on commissioning decision

In July 2017, the Public Health Commissioners decided not to re-commission the Balance course due to funding constraints. Alternative funding was sought from Mental Health Commissioners, who decided not to fund this course as the quantitative evidence to support it was insufficient, specifically that a small number of

people had completed the course. Also, it was not within their usual commissioning remit. In response to this decision, the Service initiated a new monthly group designed to be a ‘step-up’ from the Get Ready for Change course. This group will be a monthly drop-in group, which can be attended by clients who have completed Get Ready for Change. The analysis from this project will be used to inform the development of this group.

Appendix H – Service Improvement Project: Lay Summary

Why we did the study

The service ran a pilot weight management programme called “Balance”. We wanted to assess whether the course was effective and how it might be improved. The course was a Tier 2 course, meaning that it was aimed at people with a body mass index (BMI) of between 25 and 39.

What we did

We analysed two types of information to determine whether the course was effective. Group members completed questionnaires during the course, and at two points after the course had finished. We also held a small focus group with 6 group members to ask them about what they found helpful and less helpful during the course. Finally, we looked at the NICE guidelines to see whether the Balance course fitted with what these guidelines recommend for this type of service.

What we found and recommended

In terms of weight change, 6/9 people attending Balance lost weight at the end of the course, and 7/9 people had lost weight at the 6-month follow-up. Also, the person whose depression scores were in the ‘clinical’ range at the start of the course was no longer classed as ‘depressed’ at the end of the course.

Group members who came to the focus group gave positive feedback about the course. They said that that Balance was very different to other weight management groups they have been to. The particularly liked that the course did not enforce rules and restrictions on them. They felt that they had the freedom to choose how they managed their weight loss. However, no one at the group talked about how they recorded their energy intake and expenditure, and some people said that they did not like to weigh themselves often. As the best practice is to monitor yourself regularly, a recommendation was for The service to consider how they can tell people about the evidence for self-monitoring, whilst keeping the course approach that people valued.

Another finding was that some people were not ready to make changes during the course and were using the course to prepare themselves for a change in the future. A recommendation was that this is monitored during the course and that additional information is given about the repeat dieting cycle.

People who attended Balance focus group said that they found the practical exercises helpful, such as mindful eating. There is research to suggest that using mental images can help with changing eating behaviours and a recommendation was that The service could add some of these exercises to Balance.

People who attended the focus group did not think it was important to monitor weight, but that there are other more important changes to capture in the questionnaires, such as a changed mind-set and improved wellbeing. A recommendation was that The service review the outcome measures and consider adding a quality of life measure.

Finally focus group members strongly recommended that the course is made available to more people. However, as the course is not going to be extended in its current form, the service has said that the material will be used in their new drop-in group.

What did we conclude?

The group who took part in Balance had lost weight by the end of the course, but the improvements were not maintained for everyone at the 3-month and 6-month follow up point. Other benefits of taking part in Balance were increased wellbeing and improved mental health. In order to help service users lose more weight, it might be useful to tell people about the evidence for monitoring weight and energy intake and expenditure.

Appendix I – Service Improvement Project: Ethical Approval from the Mental Health Trust

Date: 27th September 2016

Dear Dr Alex Stephens & Sally McGuire

Service evaluation of a Tier 2 weight management group 'Balance'

Trust Reference: E2016.025 Stephens McGuire

This letter is to confirm that your evaluation is now approved and also provides you with our reference number.

If you do need any further support or information, please contact us using the contact details above, quoting our reference number for your study.

The importance of disseminating all evaluation work cannot be over emphasised. It is only by sharing our learning that we can improve services across the trust. For this reason, the findings of all evaluation work should be reported to the Evaluation team via email. The team will champion the results of service evaluations, and work with evaluators to ensure those results are disseminated and acted upon, and that the results of evaluations are reflected in future service delivery. The team will also work with evaluators to produce publications for the public domain.

I very much look forward to receiving the results of your evaluation in due course.

Appendix J – Service Improvement Project: Ethical Approval from The University of Bath

Dear Sally,

I am sorry for the delay getting back to you about this. There was some disagreement within the Committee about the application which needed to be resolved.

I am happy to give the study full ethical approval. Before collecting data please make the following two changes:

1. On the debrief form, under the Contact subheading, please could you add: 'If you have any concerns about the ethics of this study please contact psychology-ethics@bath.ac.uk'
2. Please ensure that the computer that you are doing the data analysis on is both password protected and encrypted. Password protection alone is not sufficient to meet the requirements of the university's data storage policies on human data (even anonymised). There are instructions on how to encrypt a device here: http://researchdata.bath.ac.uk/guide/working-with-data/sensitive-data/

Your ethics reference code for internal ethical approval is 16-218.

Best of luck with your data analysis and collection,

Dr. Nathalia Gjersoe

Chair, Psychology Ethics Committee

Appendix K – Main Research Project: Target Journal Guidelines for Authors

GUIDE FOR AUTHORS

Introduction

Cognitive and Behavioral Practice is a quarterly international journal with the primary mission of clinical dissemination: to bridge the gap between published clinical research and the actual clinical practice of cognitive and behavioral therapies. *Cognitive and Behavioral Practice* publishes clinically rich accounts of innovative assessment and therapeutic procedures that are clearly grounded in evidence-based practice. The primary focus is on application and implementation of procedures. Accordingly, topics are selected to address current challenges facing practitioners, both in terms of technique, process, and the content of treatment. To meet this goal, articles may include rich descriptions of clinical interventions, examples of client-therapist dialog, embedded video clips readers can view on line, and/or significant case descriptions. This journal is for the practicing mental health clinician, instructors, and researchers with an interest in the clinical dissemination of their findings. Continuing education examinations are included in each issue.

Types of contributions

Teaching Clinical Strategies: These papers focus on educating the readership about how to conduct assessments and/or treatments with particular populations within an empirically supported framework. They must include case illustrations and preferably will include transcript material or video demonstrations. Teaching about other aspects of Clinical Practice: These papers might deal with supervision, legal and ethical issues, managed care issues, or giving legal testimony, for instance. There is no limit on the topics as long as they are relevant to clinical practice. Research Reports: These are papers that present clinically relevant research results. They may present new data on assessment, treatment or psychopathology. If they are short articles, the authors need only to point out briefly the clinical utility of the findings. Longer papers must include detailed case illustrations and, hopefully, transcript material to make the research findings clinically realistic and immediate. Treatment Development Reports: These papers might describe the theoretical foundation and iterative process used to develop a novel intervention or describe how an established treatment is adapted to a novel population or clinical setting. These papers might highlight issues of acceptability, feasibility, and initial outcomes, but competitive papers will highlight detailed description of the structure, strategies, and techniques the treatment employs. Case examples and/or video clips of interventions are encouraged that highlight how the treatment is implemented and how barriers/challenges are addressed. Special Series: These are collections of papers focusing on a special clinical topic. There is a Series Editor who develops the theme and then invites other clinicians and scientists to write topical papers that fit into the theme. Case Conferences: Like special series, case conferences are a collection of papers that focus upon a theme; in this instance, it is how to assess and treat a particular patient. The Case Conference Organizer writes up a detailed description of a case and selects four to eight Case Conference Respondents. The Case Conference Respondents write 6- to 20-page papers describing how they would assess and treat the patient. Also, the Respondents attend to special issues involved with treatment. Typically, the Organizer writes up a summary of the similarities and differences among the approaches taken by the Respondents. Expert Clinical Commentaries: These are brief articles (solicited and unsolicited) in which experts in the field comment on the most up-to-date clinical topics, controversies, or discoveries within their expertise, and/or comment on an agenda for clinical research. These are roughly 3,000 words in length and are structured as a launching point for clinical practice and/or future clinical research. Clinical Reviews. These are regular length review articles that focus specifically on clinical strategy and existing evidence base for that strategy.

Contact details

Questions about the appropriateness of a manuscript for Cognitive and Behavioral Practice should be directed (prior to submission) to the Editorial Office, at bonnieb@bu.edu (Bonnie Brown, Editorial Assistant, Cognitive and Behavioral Practice, Center for Anxiety, Boston University, 648 Beacon Street, 6th Floor, Boston, MA 02215).

Appendix L – Main Research Project: Target: Questionnaires

Dizziness Handicap Inventory (DHI)

P1. Does looking up increase your problem?	o Yes o Sometimes o No
E2. Because of your problem, do you feel frustrated?	o Yes o Sometimes o No
F3. Because of your problem, do you restrict your travel for business or recreation?	o Yes o Sometimes o No
P4. Does walking down the aisle of a supermarket increase your problems?	o Yes o Sometimes o No
F5. Because of your problem, do you have difficulty getting into or out of bed?	o Yes o Sometimes o No
F6. Does your problem significantly restrict your participation in social activities, such as going out to dinner, going to the movies, dancing, or going to parties?	o Yes o Sometimes o No
F7. Because of your problem, do you have difficulty reading?	o Yes o Sometimes o No
P8. Does performing more ambitious activities such as sports, dancing, household chores (sweeping or putting dishes away) increase your problems?	o Yes o Sometimes o No
E9. Because of your problem, are you afraid to leave your home without having someone accompany you?	o Yes o Sometimes o No
E10. Because of your problem have you been embarrassed in front of others?	o Yes o Sometimes o No
P11. Do quick movements of your head increase your problem?	o Yes o Sometimes o No
F12. Because of your problem, do you avoid heights?	o Yes o Sometimes o No
P13. Does turning over in bed increase your problem?	o Yes o Sometimes o No
F14. Because of your problem, is it difficult for you to do strenuous homework or yard work?	o Yes o Sometimes o No
E15. Because of your problem, are you afraid people may think you are intoxicated?	o Yes o Sometimes o No
F16. Because of your problem, is it difficult for you to go for a walk by yourself?	o Yes o Sometimes o No

P17. Does walking down a sidewalk increase your problem?	o Yes o Sometimes o No
E18.Because of your problem, is it difficult for you to concentrate	o Yes o Sometimes o No
F19. Because of your problem, is it difficult for you to walk around your house in the dark?	o Yes o Sometimes o No
E20. Because of your problem, are you afraid to stay home alone?	o Yes o Sometimes o No
E21. Because of your problem, do you feel handicapped?	o Yes o Sometimes o No
E22. Has the problem placed stress on your relationships with members of your family or friends?	o Yes o Sometimes o No
E23. Because of your problem, are you depressed?	o Yes o Sometimes o No
F24. Does your problem interfere with your job or household responsibilities?	o Yes o Sometimes o No
P25. Does bending over increase your problem?	o Yes o Sometimes o No

Participant Identification Number:

Vestibular Rehabilitation Benefit Questionnaire

This questionnaire asks about your **dizziness** on a **typical day** in the last week - please do not include problems that you think are caused by another condition. Please answer all of the questions by circling **one** of the answer options.

Part A – your symptoms

This section is about how often you experience different feelings.

1. I feel dizzy						
All of the time	Very often	Quite often	Sometimes	Not very often	Only very occasionally	Never
2. I get a feeling of tingling, prickling or numbness in my body						
All of the time	Very often	Quite often	Sometimes	Not very often	Only very occasionally	Never
3. I have a feeling that things are spinning or moving around						
All of the time	Very often	Quite often	Sometimes	Not very often	Only very occasionally	Never
4. I feel as though my heart is pounding or fluttering						
All of the time	Very often	Quite often	Sometimes	Not very often	Only very occasionally	Never
5. I feel unsteady, as though I may lose my balance						
All of the time	Very often	Quite often	Sometimes	Not very often	Only very occasionally	Never
6. I have difficulty breathing or feel short of breath						
All of the time	Very often	Quite often	Sometimes	Not very often	Only very occasionally	Never

This section is about how dizzy you get when you move around. Please do not circle 'not at all dizzy' if you avoid making the movement - either try the movement or talk to your balance therapist before answering.

7. Bending over makes me feel

Not at all dizzy	Very slightly dizzy	Mildly dizzy	Moderately dizzy	Really quite dizzy	Very dizzy	Extremely dizzy

8. Lying down and/or turning over in bed makes me feel

Not at all dizzy	Very slightly dizzy	Mildly dizzy	Moderately dizzy	Really quite dizzy	Very dizzy	Extremely dizzy

9. Looking up at the sky makes me feel

Not at all dizzy	Very slightly dizzy	Mildly dizzy	Moderately dizzy	Really quite dizzy	Very dizzy	Extremely dizzy

10. Moving my head slowly from side to side makes me feel

Not at all dizzy	Very slightly dizzy	Mildly dizzy	Moderately dizzy	Really quite dizzy	Very dizzy	Extremely dizzy

11. Moving my head quickly from side to side makes me feel

Not at all dizzy	Very slightly dizzy	Mildly dizzy	Moderately dizzy	Really quite dizzy	Very dizzy	Extremely dizzy

Part B – how the dizziness is affecting you

Please read each question carefully - some of the statements are phrased to suggest that you have difficulty (for example, 'I have trouble focusing my eyes') and some are phrased to suggest you do not have difficulty (for example, 'I feel comfortable travelling'). If a question does not apply to you, please circle 'same as before' rather than leaving it out.

12. Compared to before the dizziness, I feel comfortable travelling

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

13. Compared to before the dizziness, I feel confident

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

14. Compared to before the dizziness, I have difficulty looking after myself (for example, washing my hair, cleaning my teeth, dressing myself, etc.)

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

15. Compared to before the dizziness, I feel comfortable going out alone

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

16. Compared to before the dizziness, I can concentrate and/or remember things

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

17. Compared to before the dizziness, I need to hold on to something for support

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

18. Compared to before the dizziness, I think my quality of life is good

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

19. Compared to before the dizziness, I avoid some activities, positions or situations

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

20. Compared to before the dizziness, I am happy to be on my own

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

21. Compared to before the dizziness, I feel stable in the dark or when my eyes are closed

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

22. Compared to before the dizziness, I take part in social activities

A lot more	Quite a bit more	A little bit more	Same as before	A little bit less	Quite a bit less	A lot less

IRAS 218894; 5th March 2017

Participant Identification Number:

Physical Symptoms and Behaviour

This questionnaire is about how physical symptoms may have impacted your behaviour. As people are very different, there are no right or wrong responses for these questions. Please indicate how much you agree or disagree with the following statements about physical symptoms by circling a number on the scale. Please circle only one box per line.

1. I eat specific foods/drink specific beverages to help me to manage my symptoms:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

2. I avoid certain food/beverages to help me manage my symptoms:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

3. I ask for reassurance about my symptoms:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

4. I am constantly aware of my symptoms:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

5. I spend a long time thinking over and over about my problems:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

6. I avoid attending social activities because of my symptoms:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

7. I would like to achieve things at work/school, but I have to set limits because of my symptoms:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

8. In order to avoid feelings of disappointment, I just try not to set myself goals or make plans:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

9. Rather than try new activities, I tend to stick with the things I know:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

10. I do not answer the phone in case people are calling with social invitations:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

11. I quit activities that challenge me too much:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

12. While I know I should make decisions about my personal relationships, I just let things go on as they are:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

13. Because of my symptoms I avoid trying new activities that hold the potential for failure:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

14. I am constantly trying to find a cause or a solution for my symptoms:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

15. I frequently attend the GP:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

16. I avoid the GP:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

17. I avoid talking about my symptoms:											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

18. When my symptoms are not as bad, I make the most of it and do as many things as I can (e.g. work, hobbies, socialising):											
Strongly disagree	1	2	3	4	5	6	7	8	9	10	Strongly agree

Participant Identification No: **Short Dizziness Beliefs Scale**

For each of the questions below, select the response which best characterizes how you feel about each statement. Response options are: 1 = Strongly agree; 2 = Agree; 3 = Neither agree nor disagree; 4 = Disagree; 5 = Strongly disagree.

When I am dizzy...	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I will let people down.	1	2	3	4	5
I will become very ill.	1	2	3	4	5
I will lose control.	1	2	3	4	5
The dizziness is a sign that there is something seriously wrong with me.	1	2	3	4	5
I will hurt myself by stumbling or falling over.	1	2	3	4	5
I will faint or pass out.	1	2	3	4	5
I will do something embarrassing.	1	2	3	4	5
I will be unable to behave normally in public.	1	2	3	4	5
I have a serious disease that no one understands.	1	2	3	4	5
I will fall over.	1	2	3	4	5
I will be unable to manage potentially dangerous activities e.g., crossing the road, walking downstairs, driving).	1	2	3	4	5

IRAS 218894; 5th March 2017
Participant Identification Number:

HAI

Each question is this section consists of a group of four statements. Please read each group of statements carefully and then select the one which best describes your feelings, over the past six months (or other agreed time period). Identify the statement by ringing the letter next to it, i.e. if you think that statement *a.)* is correct, ring statement *a.)*. It may be that more than one statement applies, in which case, please ring any that are applicable.

1. *a.)* I do not worry about my health.
b.) I occasionally worry about my health.
c.) I spend much of my time worrying about my health.
d.) I spend most of my time worrying about my health.

2. *a.)* I notice aches/pains less than most other people (of my age).
b.) I notice aches/pains as much as most other people (of my age).
c.) I notice aches/pains more than most other people (of my age).
d.) I am aware of aches/pains in my body all the time.

3. *a.)* as a rule I am not aware of bodily sensations or changes.
b.) sometimes I am aware of bodily sensations or changes.
c.) I am often aware of bodily sensations or changes.
d.) I am constantly aware of bodily sensations or changes.

4. *a.)* resisting thoughts of illness is never a problem.
b.) most of the time I can resist thoughts of illness.
c.) I try to resist thoughts of illness but am often unable to do so.
d.) thoughts of illness are so strong that I no longer even try to resist them.

5. *a.)* as a rule I am not afraid that I have a serious illness.
b.) I am sometimes afraid that I have a serious illness.
c.) I am often afraid that I have a serious illness.
d.) I am always afraid that I have a serious illness.

6. *a.)* I do not have images (mental pictures) of myself being ill.
b.) I occasionally have images of myself being ill.
c.) I frequently have images of myself being ill.
d.) I constantly have images of myself being ill.

7. *a.)* I do not have any difficulty taking my mind off thoughts about my health.
b.) I sometimes have difficulty taking my mind off thoughts about my health.
c.) I often have difficulty in taking my mind off thoughts about my health.
d.) Nothing can take my mind off thoughts about my health.

8. *a.)* I am lastingly relieved if my doctor tells me there is nothing wrong.
b.) I am initially relieved but the worries sometimes return later.
c.) I am initially relieved but the worries always return later.
d.) I am not relieved if my doctor tells me there is nothing wrong.

9. *a.)* if I hear about an illness I never think I have it myself.
b.) if I hear about an illness I sometimes think I have it myself.
c.) if I hear about an illness I often think I have it myself.
d.) if I hear about an illness I always think I have it myself.

10. *a.)* if I have a bodily sensation or change I rarely wonder what it means.
b.) if I have a bodily sensation or change I often wonder what it means.
c.) if I have a bodily sensation or change I always wonder what it means.
d.) if I have a bodily sensation or change I must know what it means.

[cont.]

11. a.) I usually feel at very low risk for developing a serious illness.
b.) I usually feel at fairly low risk for developing a serious illness.
c.) I usually feel at moderate risk for developing a serious illness.
d.) I usually feel at high risk for developing a serious illness.

12. *a.)* I never think I have a serious illness.
b.) I sometimes think I have a serious illness.
c.) I often think I have a serious illness.
d.) I usually think that I am seriously ill.

13. *a.)* if I notice an unexplained bodily sensation I don't find it difficult to think about other things.
b.) if I notice an unexplained bodily sensation I sometimes find it difficult to think about other things.
c.) if I notice an unexplained bodily sensation I often find it difficult to think about other things.
d.) if I notice an unexplained bodily sensation I always find it difficult to think about other things.

14. *a.)* my family/friends would say I do not worry enough about my health.
b.) my family/friends would say I have a normal attitude to my health.
c.) my family/friends would say I worry too much about my health.
d.) my family/friends would say I am a hypochondriac.

For the following questions, please think about what it might be like if you had a serious illness of a type which particularly concerns you (e.g. heart disease, cancer, multiple sclerosis & so on). Obviously you cannot know for definite what it would be like; please give your best estimate of what you *think* might happen, basing your estimate on what you know about yourself and serious illness in general.

15. *a.)* if I had a serious illness I would still be able to enjoy things in my life quite a lot.
b.) if I had a serious illness I would still be able to enjoy things in my life a little.
c.) if I had a serious illness I would be almost completely unable to enjoy things in my life.
d.) if I had a serious illness I would be completely unable to enjoy life at all.

16. *a.)* if I developed a serious illness there is a good chance that modern medicine would be able to cure me.
b.) if I developed a serious illness there is a moderate chance that modern medicine would be able to cure me.
c.) if I developed a serious illness there is a very small chance that modern medicine would be able to cure me.
d.) if I developed a serious illness there is no chance that modern medicine would be able to cure me.

17. *a.)* a serious illness would ruin some aspects of my life.
b.) a serious illness would ruin many aspects of my life.
c.) a serious illness would ruin almost every aspect of my life.
d.) a serious illness would ruin every aspect of my life.

18. *a.)* if I had a serious illness I would not feel that I had lost my dignity.
b.) if I had a serious illness I would feel that I had lost a little of my dignity.
c.) if I had a serious illness I would feel that I had lost quite a lot of my dignity.
d.) if I had a serious illness I would feel that I had totally lost my dignity.

Participant Identification Number:

BVS

This scale is designed to index how sensitive you are to internal bodily sensations such as heart palpitations or dizziness. Fill it out according to how you have felt for the **past week**.

1. "I am the kind of person who pays close attention to internal body sensations."

0	1	2	3	4	5	6	7	8	9	10
Not at all					Somewhat					Extremely

2. "I am very sensitive to **changes** in my internal body sensations."

0	1	2	3	4	5	6	7	8	9	10
Not at all					Somewhat					Extremely

3. "On average, **how much time** do you spend each day scanning your body for sensations?"

0	10	20	30	40	50	60	70	80	90	100
Never					Half the time					Constantly

4. Rate how much attention you pay to each of the following sensations using this scale:

0	1	2	3	4	5	6	7	8	9	10
none		slight			moderate			substantial		extreme

1. _____ heart palpitations
2. _____ chest pain/discomfort
3. _____ numbness
4. _____ tingling
5. _____ shortness of breath/smothering
6. _____ faintness
7. _____ vision changes
8. _____ feelings of unreality
9. _____ feeling detached from the self
10. _____ dizziness
11. _____ hot flash
12. _____ sweating/clammy hands
13. _____ upset stomach
14. _____ nausea
15. _____ choking/throat closing

Participant Identification Number:

GAD-7 Anxiety

Over the last 2 weeks, how often have you been bothered by the following problems? *Circle the number to indicate your answer.*	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Participant Identification Number:

PHQ-9 Depression

Over the last 2 weeks, how often have you been bothered by any of the following problems? Please circle your answer.

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3
Trouble falling or staying asleep, or sleeping too much	0	1	2	3
Feeling tired or having little energy	0	1	2	3
Poor appetite or overeating	0	1	2	3
Feeling bad about yourself — or that you are a failure or have let yourself or your family down.	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

Appendix M – Main Research Project: Target: Expression of Interest Form

IRAS 218894; 5th March 2017

Participant Identification Number:

Department of **Psychology** | UNIVERSITY OF BATH

v1.0

Building 10 West 3.42
Claverton Down
Bath BA2 7AY

Email: sally.mcguire@nhs.net

EXPRESSION OF INTEREST FOR PARTICIPATING IN RESEARCH

During the assessment appointment, you have been given information about a research study about the factors that predict recovery from symptoms of dizziness, vertigo and imbalance.

If you would like to participate, or if you would like further information before you decide whether to participate, please complete the table below. Please provide contact information that you are happy for us to use to contact you. Please return the form to the person who gave it to you.

Full name	
Address	
Mobile phone number	
Home phone number	
Email address	
Date of birth	

Please select:

I am interested in participating in this research study, but I would like to speak with a researcher beforehand, to obtain further information. *If you select "Yes" to this question, you will be contacted by a researcher within 5 days of completing this form.*	Yes/No *(please specify)*
I consent to being contacted by the researcher by phone	Yes/No *(please specify)*
I consent to being contacted by the researcher by email	Yes/No *(please specify)*
I consent to being contacted by the researcher by post.	Yes/No *(please specify)*

If you DO NOT require further information about the study, please read the Information Sheet and Consent Form in the stapled pack before completing the questionnaires. Thank you for your interest in participating in the research.

Staff use only:

Recruiting staff member: Please record the following information on the log:

Participant I.D. number:

Hospital number:

Date of appointment:

Recruiting clinician:

Patient name; gender; date of birth:

First assessment for this problem:

Symptom duration:

Current vestibular disorder diagnosis? (Specify and include tinnitus and hearing loss):

Any previous vestibular disorder diagnoses that no longer apply? (Specify):

Current use of vestibular suppressants (Yes/No):

Was information about vestibular compensation provided during the assessment (Yes/No):

Appendix N – Main Research Project: Target: Participant Information Sheet

IRAS 218894; 21st June 2017

v1.1

University College London Hospitals NHS
NHS Foundation Trust

Department of Psychology | University of Bath

Building 10 West 3.42
Claverton Down
Bath BA2 7AY

Participant Information Sheet

Which factors predict recovery or persistence of dizziness following assessment at an NHS clinic?

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. You can talk to other people about the study if you wish.

***Part 1** tells you the purpose of this study and what will happen if you take part. **Part 2** gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear.*

Information Sheet Part 1: Purpose of the Study

Purpose of the study

Dizziness, vertigo and imbalance are common problems for which people seek help from healthcare professionals. This research aims help us understand what might make people more or less likely to experience symptoms, and recover from them.

The project will help us understand what factors predict the persistence of dizziness. This information could be used to inform clinical practice. For example, it might tell us which patients with dizziness could benefit from receiving certain treatments.

Why have I been invited?

You have been invited to take part because you have attended an assessment appointment at an NHS Audiology clinic and you are experiencing dizziness, vertigo and / or imbalance.

Do we have to take part?

No, it is up to you to decide. If you do want to take part, then you'll be asked to sign a consent form, a copy of which is attached to this information sheet. Even if you do consent to join the study, you will be free to withdraw at any point without giving us a reason. You will not be treated any differently by any NHS service if you choose not to participate in this study or if you decide to withdraw.

What the study will involve?

If you choose to take part, you will be asked to complete a set of questionnaires within 7 days of your assessment appointment. You will then be asked to complete a much shorter set of questionnaires 6 months later.

The questionnaires can be completed either online or on paper. Paper questionnaires may be completed at the clinic after your NHS assessment appointment or at home. Once completed, they should be posted to the University of Bath using a pre-paid envelope, within 7 days of your assessment appointment.

The first set of questionnaires will take approximately 25 minutes to fill in, and the second set of questionnaires (at 6 months) will take approximately 5 minutes to fill in.

Expenses and payments

As a thank you for taking part, we are giving participants a £5 retail voucher for filling in the questionnaires. You will receive this when we have received your first set of completed questionnaires.

Might anything about the research upset me?

We do not think that it is likely that the people taking part in our study will become distressed as a result of completing the questionnaires.

However, if you have any concerns about your health following completion of the questionnaires, you should contact your GP for advice.

What are the possible benefits of taking part?

There is no intended direct benefit to taking part in this study. The hope that the information we get from this study will help to improve the support that is available to other people who experience similar symptoms.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

Risk of harm

If you indicate any risk of harm to yourself or other people through your answer to the questionnaires or in conversation with the Researcher, relevant information will be shared with your GP and the project supervisors. You will be informed before this happens.

Information Sheet Part 2: Study Conduct

Who is running this study?

The study is being run by the University of Bath. The information collected will in part fulfil an educational requirement for the Clinical Psychologist in Training who is completing a Doctorate in Clinical Psychology at the University of Bath.

Confidentiality

All information collected during the research will be kept strictly confidential. The Expression of Interest forms which gave you initial information about this project will be kept in locked cabinets at the Audiology Clinic. Paper questionnaires will be stored in locked cabinets at the University of Bath and will only be accessed by the main researcher and the project supervisors. The data provided in the questionnaires that you complete will be stored electronically under an anonymous ID number on an encrypted and password protected computer. Your name will not be kept with your data. The only time that we would share your information without your agreement is if we believe that you or someone else is at serious risk of harm. In this case, we would talk to you first and we would follow the standard protocol of the NHS audiology department of which you are a patient.

Your questionnaires will be kept in locked storage at the University of Bath for 5 years following completion of the study after which it will be destroyed. The consent form includes a request for your permission to keep personal contact details in our records so that we can contact you again after the study has finished if needed. Personal contact details will be stored separately from questionnaires. It is up to you whether or not you agree to your details being kept for this purpose.

The results of the study may be published in a scientific journal and/or at an academic conference but we would not publish any details that might identify you.

What happens to our information if we withdraw from the study?

If you withdraw from the study it is up to you whether we use any information we have already collected. If you want your information to be removed from the study then you just need to let us know and your questionnaires will be destroyed.

Has this research study been approved by an ethics committee?

Yes, this study has received a favourable ethics opinion from the East Midlands-Derby Research Ethics Committee (Ref: 17/EM/0172) and the University of Bath Psychology Research Ethics Committee.

I have some questions about this study, who do I contact?

You can contact the researcher, Sally McGuire, who is a Clinical Psychologist in Training at the University of Bath. Her email address is: sally.mcguire@nhs.net

What if I am not happy about the research study?

If you have a concern about any aspect of this study, you can speak to the project supervisor Dr. Elizabeth Marks. Her contact details are: Dr. Elizabeth Marks, Research Supervisor, University of Bath address: Department of Psychology, University of Bath, Bath BA2 7AY. Email: E.Marks@bath.ac.uk

Thank you very much for reading this information sheet.

Appendix O – Main Research Project: Target: Consent Form

IRAS 218894; 5th May 2017

v1.1

Department of Psychology
UNIVERSITY OF BATH

Building 10 West 3.42
Claverton Down
Bath BA2 7AY

Email: sally.mcguire@nhs.net

Participant Identification Number:

CONSENT FORM

Title of Project: Which cognitive-behavioural factors predict the persistence of dizziness following assessment at an NHS vestibular clinic?

Name of Researcher: Sally McGuire, Clinical Psychologist in Training, University of Bath.

Please initial box to consent:

1. I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that the information I provide is confidential and will not be shared with anyone else. However, if I provide any information that suggests that I am at risk of harm I am aware that the researcher would need to pass this information on to relevant professionals, including my GP. ☐
4. I understand that the results of this study may be published in a scientific paper. Publications will only use anonymised data. ☐
5. I agree to being contacted by the researcher: by telephone ☐

6. I agree to being contacted by the researcher: by email ☐

7. I agree to being contacted by the researcher: by post ☐

8. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
_____	_____	_____

Please return this form along with your completed questionnaires.

This original document will be stored securely at the University of Bath. You may also like to take a copy for your own records.

Appendix P – Main Research Project: Target: Ethical Approval from the Research Ethics Committee

NHS
Health Research Authority
East Midlands - Derby Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

04 May 2017

Miss Sally McGuire
Department of Psychology, University of Bath
Claverton Down Road
Bath
BA2 7AY

Dear Miss McGuire,

Study title:	**Which cognitive-behavioural factors predict the persistence of dizziness following assessment at an NHS vestibular clinic?**
REC reference:	**17/EM/0172**
Protocol number:	**N/A**
IRAS project ID:	**218894**

The Proportionate Review Sub-committee of the East Midlands - Derby Research Ethics Committee reviewed the above application on 04 May 2017.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Please replace 'tick' with 'initial' on the consent form.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

- **Informed consent process and the adequacy and completeness of participant information**

  The Sub-Committee agreed there should be instructions to 'initial' rather than 'tick' on the consent form.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Univ. of Bath Insurance]		11 April 2017
IRAS Application Form [IRAS_Form_20042017]		20 April 2017
IRAS Application Form XML file [IRAS_Form_20042017]		20 April 2017
IRAS Checklist XML [Checklist_20042017]		20 April 2017
IRAS Checklist XML [Checklist_24042017]		24 April 2017
Letter from sponsor [Bath Univ Sponsorship Approval]	1.0	12 April 2017
Letters of invitation to participant [Expression of Interest Form]	1.0	05 March 2017
Non-validated questionnaire [Mental health history questionnaire]	1.0	05 March 2017
Non-validated questionnaire [Behaviour-P Questionnaire]	1.0	05 March 2017
Other [Debrief Sheet]	1.0	05 March 2017
Other [HRA Statement of Activities]	1.0	11 April 2017
Other [HRA Schedule of Events]	1.0	11 April 2017
Other [Signed CV Sally McGuire page 1 of 2]	1.0	23 February 2017
Other	1.0	23 February 2017
Participant consent form [Participant Consent Form]	1.0	05 March 2017
Participant information sheet (PIS) [Participant Information Sheet]	1.0	05 March 2017
Research protocol or project proposal [Research Protocol]	1.0	05 March 2017
Summary CV for Chief Investigator (CI) [Sally McGuire CV]	1.0	12 April 2017
Summary CV for student [Sally McGuire CV]	1.0	12 April 2017

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Please replace 'tick' with 'initial' on the consent form.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

Summary CV for supervisor (student research) [CV_ E Marks]	1.0	23 February 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Lay Summary]		05 March 2017
Validated questionnaire [GAD7]	1.0	05 March 2017
Validated questionnaire [Health Anxiety Inventory]	1.0	05 March 2017
Validated questionnaire [Patient Health Questionnaire]	1.0	05 March 2017
Validated questionnaire [Short Dizziness Beliefs Scale]	1.0	05 March 2017
Validated questionnaire [Dizziness Handicap Inventory]	1.0	
Validated questionnaire [VRBQ]	1.0	

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

17/EM/0172 **Please quote this number on all correspondence**

Yours sincerely

PP
Mr Peter Korczak (Chair)
Chair

Email: NRESCommittee.EastMidlands-Derby@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers" SL-AR2

Copy to: *Prof Jonathan Knight*

Appendix Q – Main Research Project: Target: Ethical Approval from the Health Research Authority and amendments

HRA Approval

16 May 2017

Dear Miss McGuire

Letter of HRA Approval

Study title:	**Which cognitive-behavioural factors predict the persistence of dizziness following assessment at an NHS vestibular clinic?**
IRAS project ID:	**218894**
REC reference:	**17/EM/0172**
Sponsor	**University of Bath**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Amendment 1 - 11th September 2017

Amendment Categorisation and Implementation Information

Dear Miss McGuire,

Thank you for submitting an amendment to your project.

If you have participating NHS/HSC organisations in any other UK nations that are affected by this amendment we will forward the information to the relevant national coordinating function(s).

Please note that you may only implement changes described in the amendment notice.

What Happens Next?

Information Specific to Participating NHS Organisations in England

1. **This email also constitutes HRA Approval for the amendment**, and you should not expect anything further from the HRA.
2. You may implement this amendment immediately.
3. You should ensure that participating NHS organisations in England are informed of this amendment. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team.
4. Participating NHS organisations in England should prepare to implement this amendment, where expected.

IRAS Project ID:	218894
Short Study Title:	Cognitive-behavioural predictors of dizziness persistence
Date complete amendment submission received:	11/09/2017
Amendment No./ Sponsor Ref:	Body Vigilance Scale
Amendment Date:	11 September 2017
Amendment Type:	Non-substantial
Outcome of HRA Assessment	**This email also constitutes HRA Approval for the amendment,** and you should not expect anything further from the HRA.
For NHS/HSC R&D Office information	
Amendment Category	**C**

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net.

If you have any questions relating this amendment in one of the devolved administrations, please direct these to the relevant national coordinating function.

Additional information on the management of amendments can be found in the IRAS guidance.

Please do not hesitate to contact me if you require further information.

Kind regards

Ali Hussain
Amendments Coordinator

Amendment 2 – 1st December 2017

Dear Miss McGuire

Further to the below, I am pleased to confirm **HRA Approval** for the referenced amendment.

You should implement this amendment at NHS organisations in England, in line with the conditions outlined in your categorisation email.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Ashley

Ashley Totenhofer
Technical Assurance Officer
Health Research Authority
HRA Centre Manchester | 3rd Floor, Barlow House | 4 Minshull Street, Manchester | M1 3DZ
T. 0207 104 8017
E. ashley.totenhofer@nhs.net
W. www.hra.nhs.uk

IRAS Project ID:	218894
Short Study Title:	Cognitive-behavioural predictors of dizziness persistence
Date complete amendment submission received:	01/12/2017
Amendment No./ Sponsor Ref:	End date to 31/12/18 & Posters
Amendment Date:	01 December 2017
Amendment Type:	Non-substantial
Outcome of HRA Assessment	**HRA Approval for the amendment is pending.** The HRA will separately confirm HRA Approval for the amendment by email.
Implementation date in NHS organisations in England	35 days from date amendment information together with this email, is supplied to participating organisations
For NHS/HSC R&D Office information	
Amendment Category	**A**

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net
If you have any questions relating to this amendment in one of the devolved administrations, please direct these to the relevant national coordinating function.
Additional information on the management of amendments can be found in the IRAS guidance.
Please do not hesitate to contact me if you require further information.

Kind regards

Ali Hussain
Amendments Coordinator
Health Research Authority

Appendix R – Main Research Project: Target: Ethical Approval from The University of Bath

Dear Sally,

Ethics code 17-135 Cognitive-behavioural predictors of dizziness persistence

I am happy to confirm that you have received full ethical approval from the University of Bath Department of Psychology Ethics Committee for your application. In light of the fact that this project has previously received ethical approval from the NHS, this approval has been granted via Chair's Action. Please use the code 17-135 as proof of ethical approval on internal documentation.
Best of luck with your research,

Dr. Nathalia Gjersoe
Chair, Psychology Ethics Committee